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(54) **EXPANDABLE INTERVERTEBRAL IMPLANT AND ASSOCIATED METHOD OF MANUFACTURING THE SAME**

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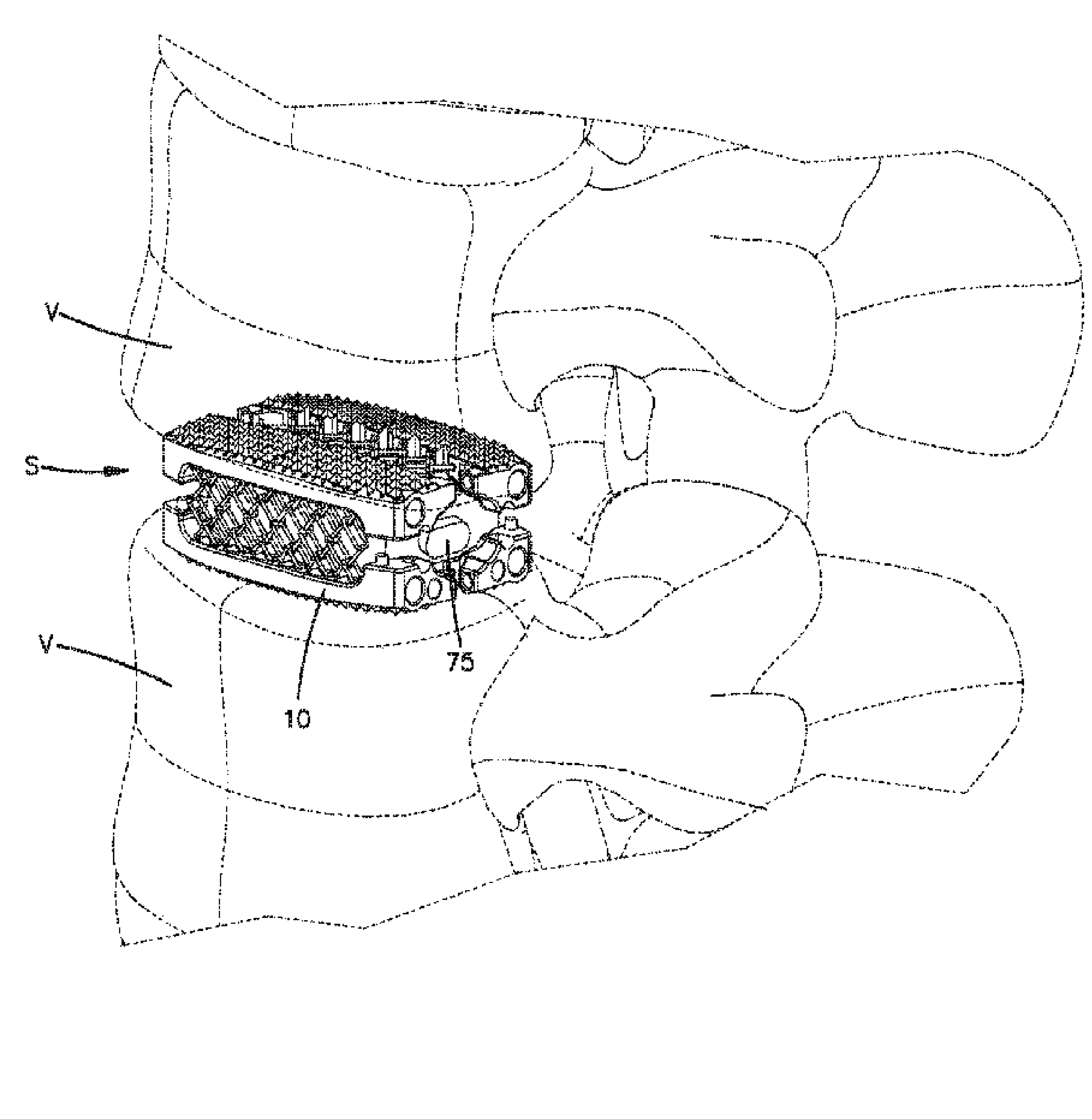
(57) **ABSTRACT**

An expandable intervertebral implant (**10**) includes superior (**20**) and inferior (**30**) bone contacting members and at least one vertical wire netting (**50**) interconnecting the superior and inferior bone contacting members. The superior and inferior bone contacting members include at least two bone contacting components interconnected via one or more lateral wire nettings such that the implant is vertically and laterally expandable in situ from a first insertion configuration to a second expanded configuration. The vertical and lateral wire netting are preferably constructed of a plurality of individual link members. The present invention also preferably relates to an associated method of manufacturing the intervertebral implant such that the intervertebral implant can be manufactured as an integral component or part.

16 Claims, 19 Drawing Sheets



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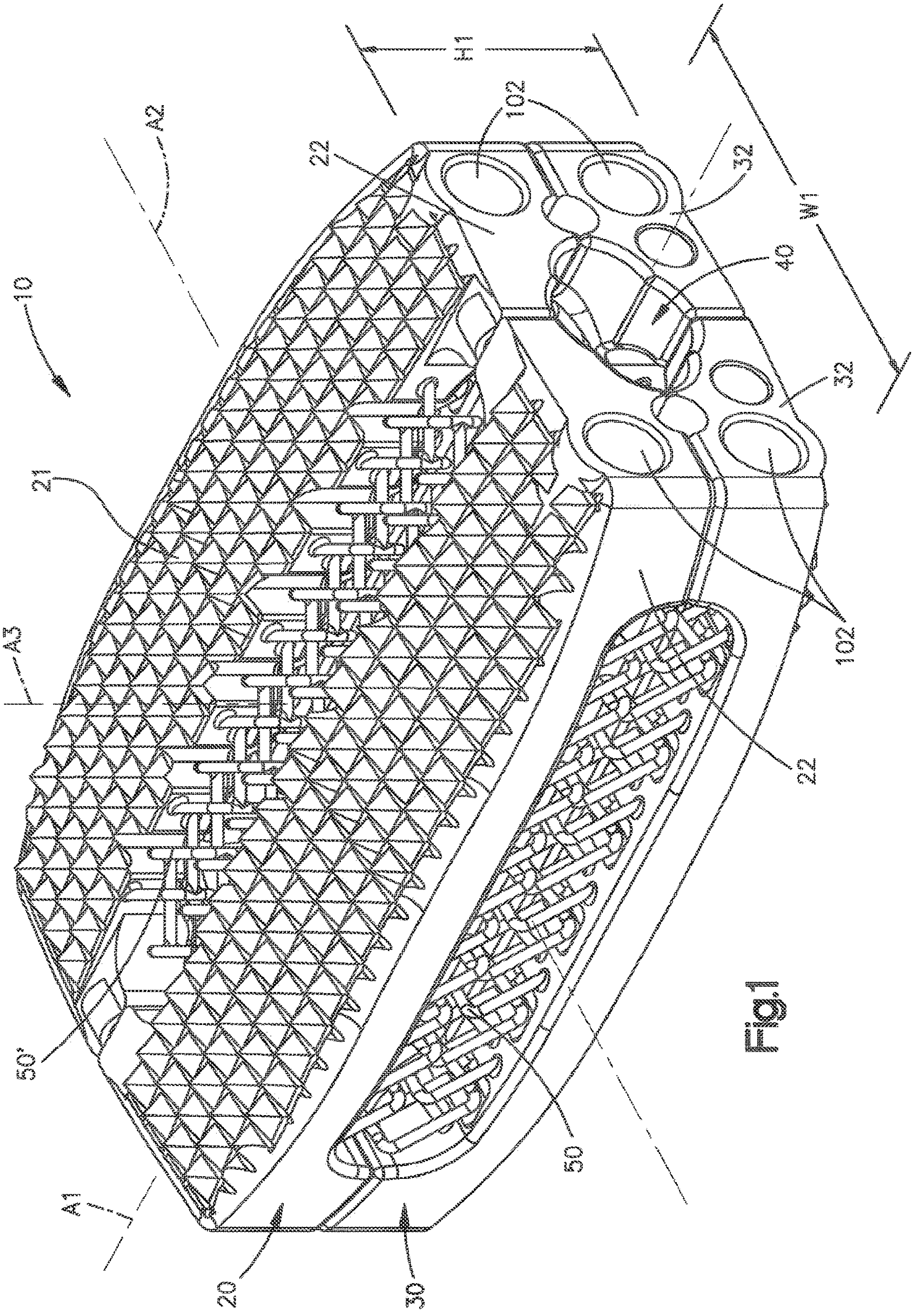

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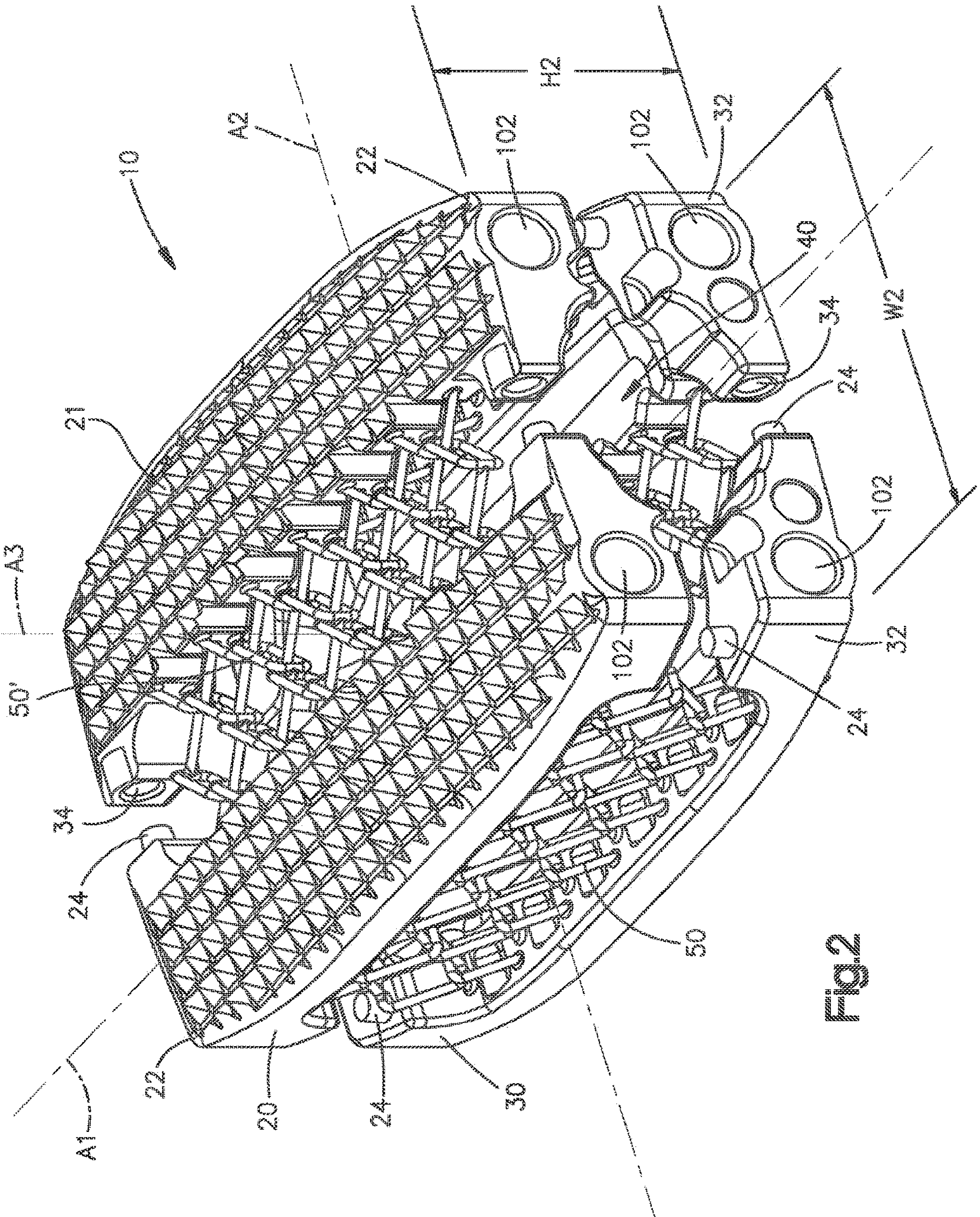
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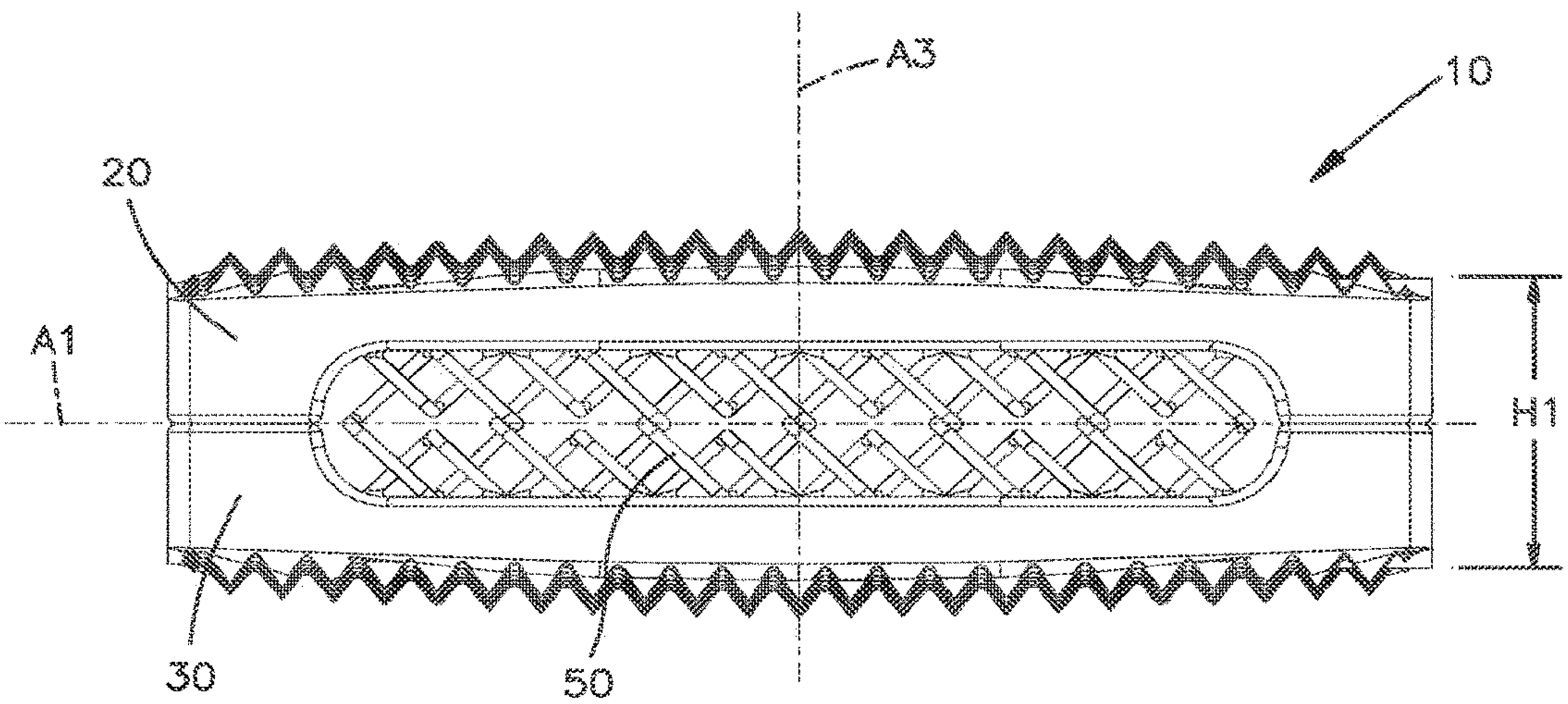
Fig.2



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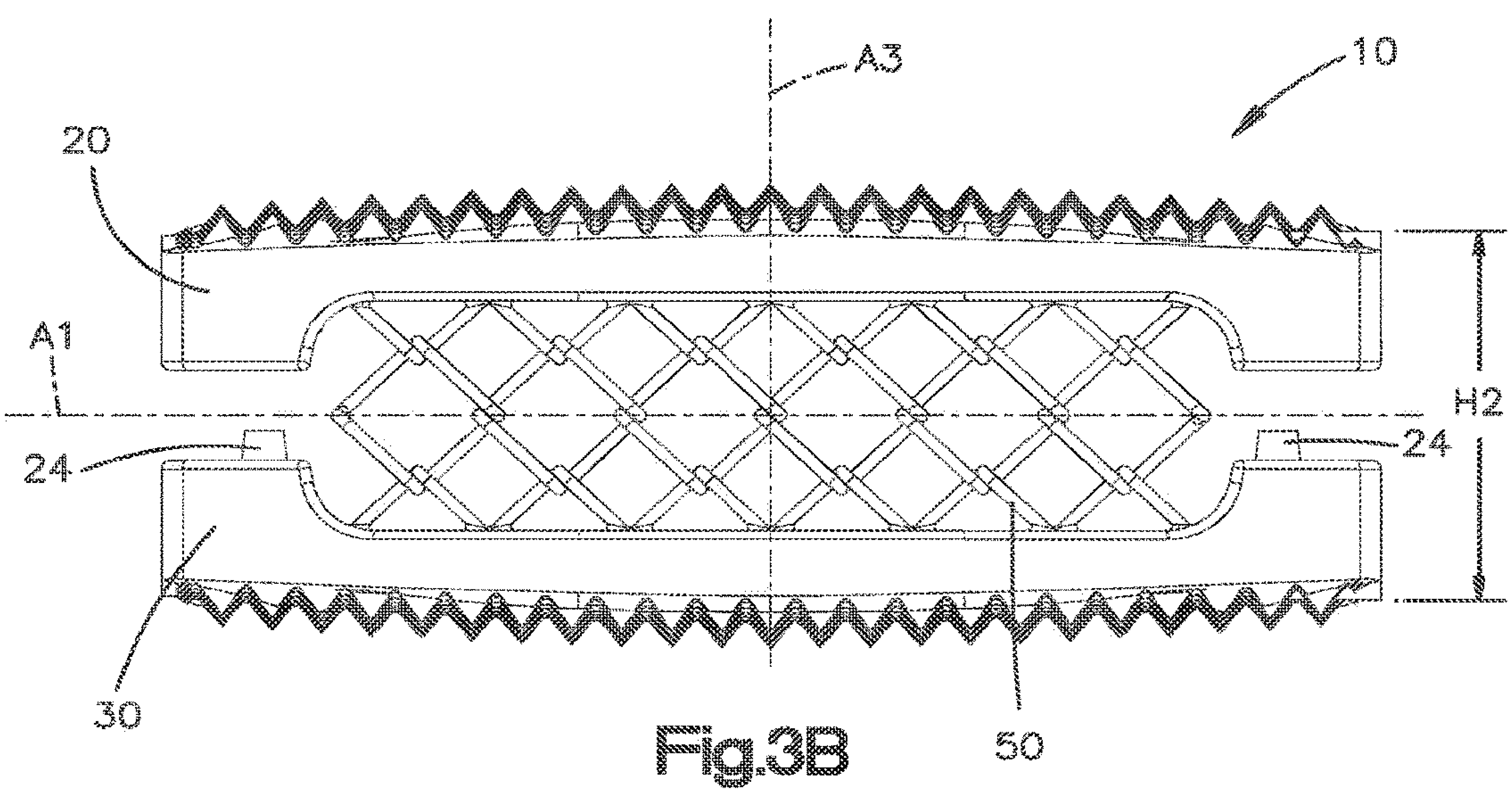

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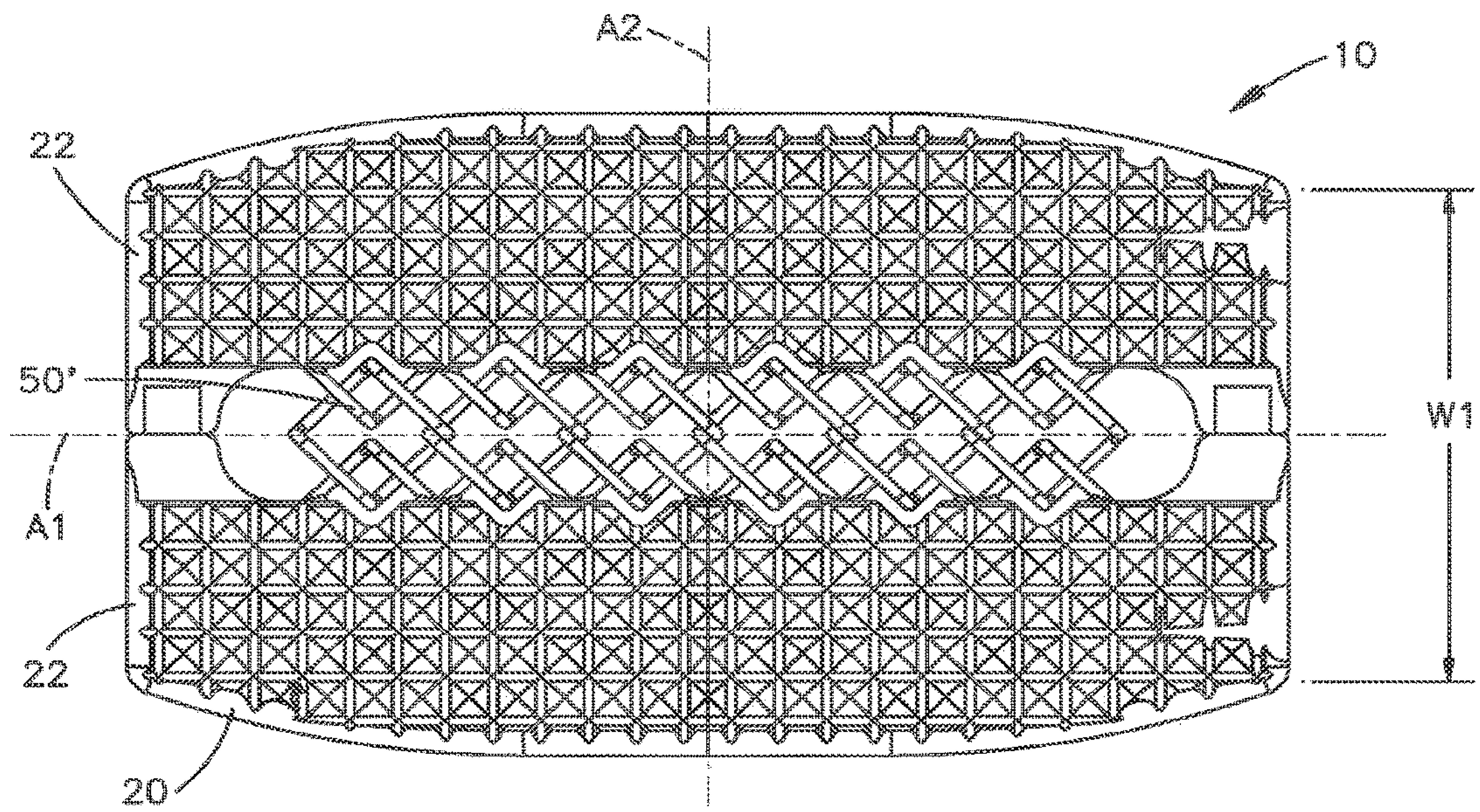

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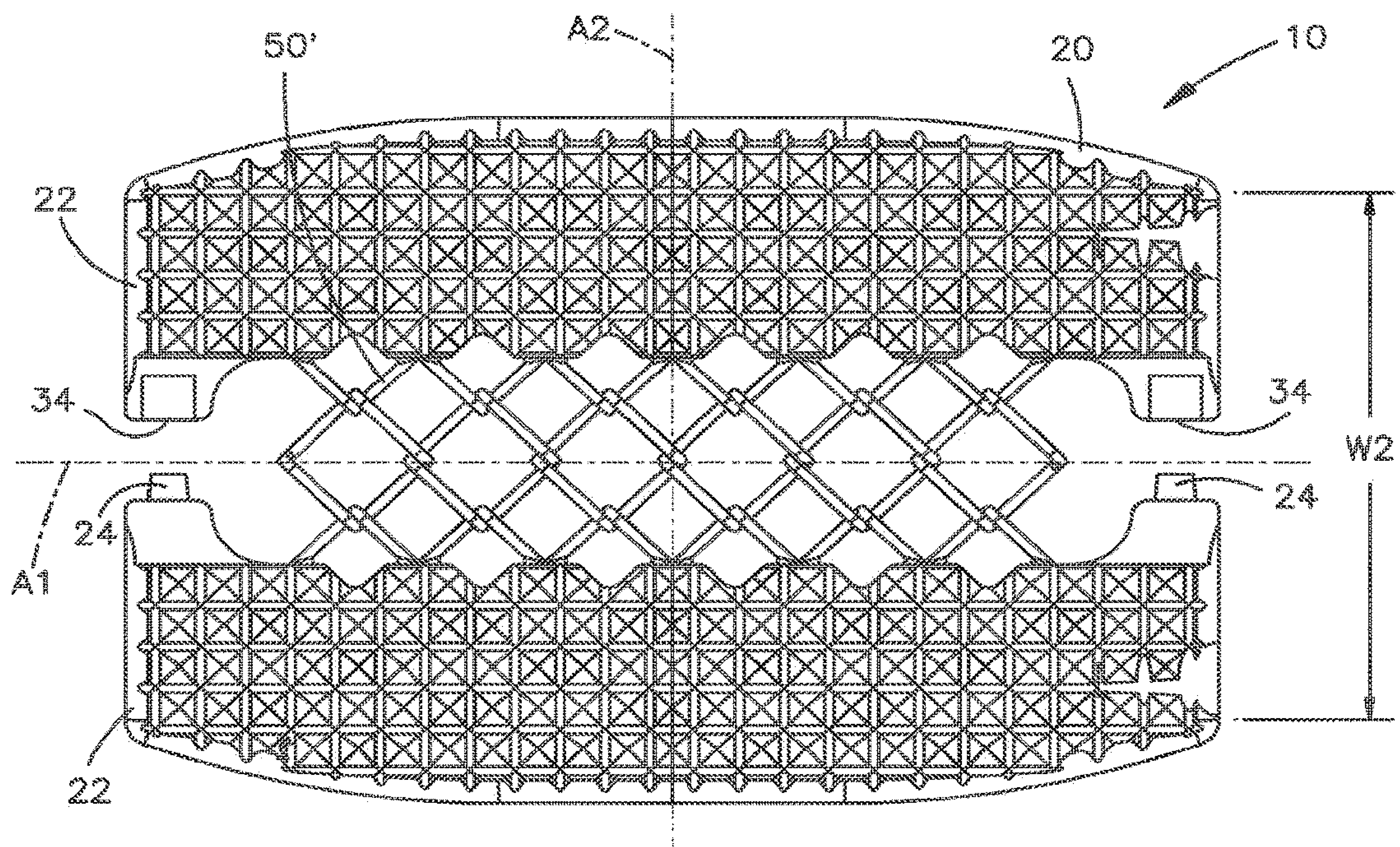

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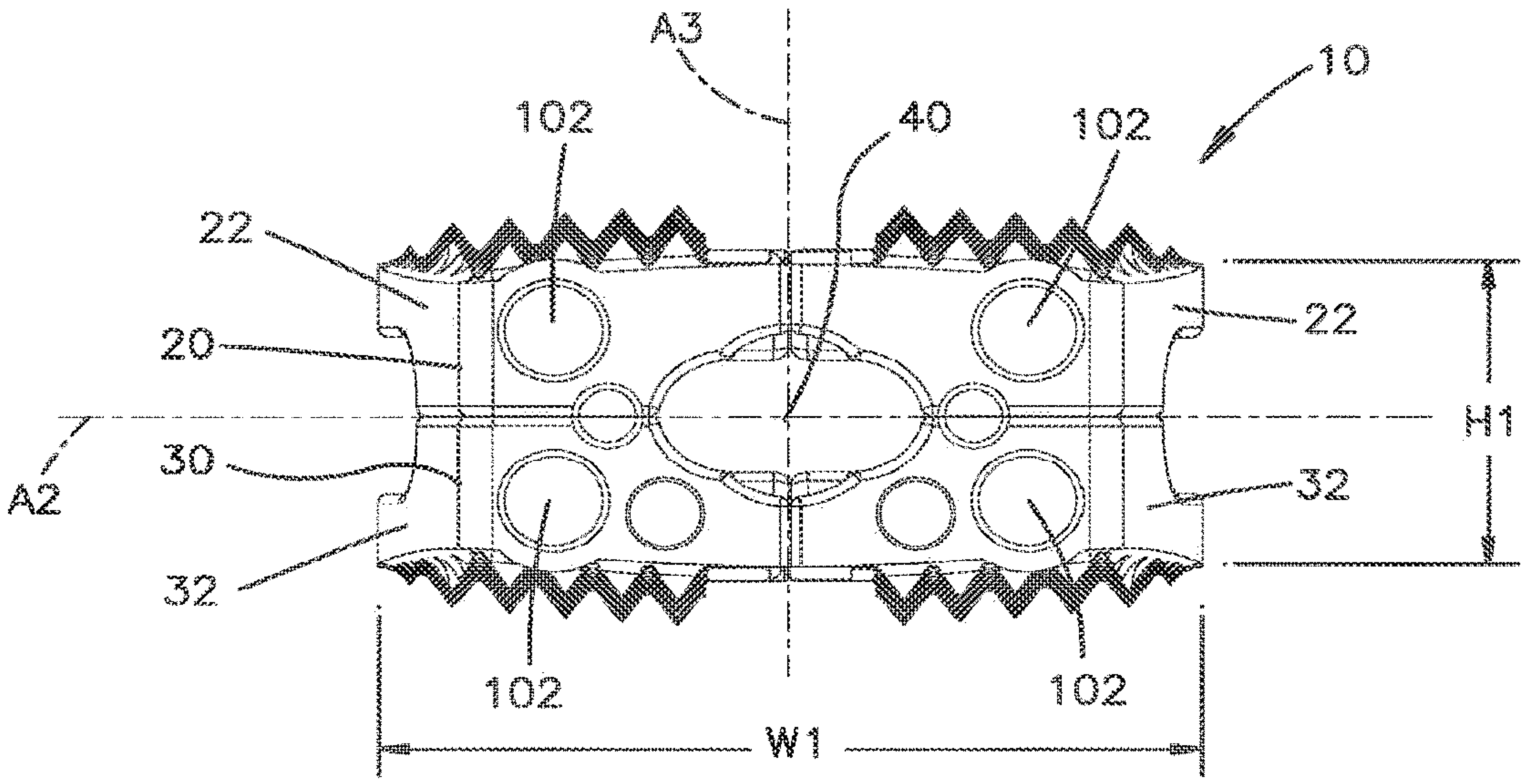
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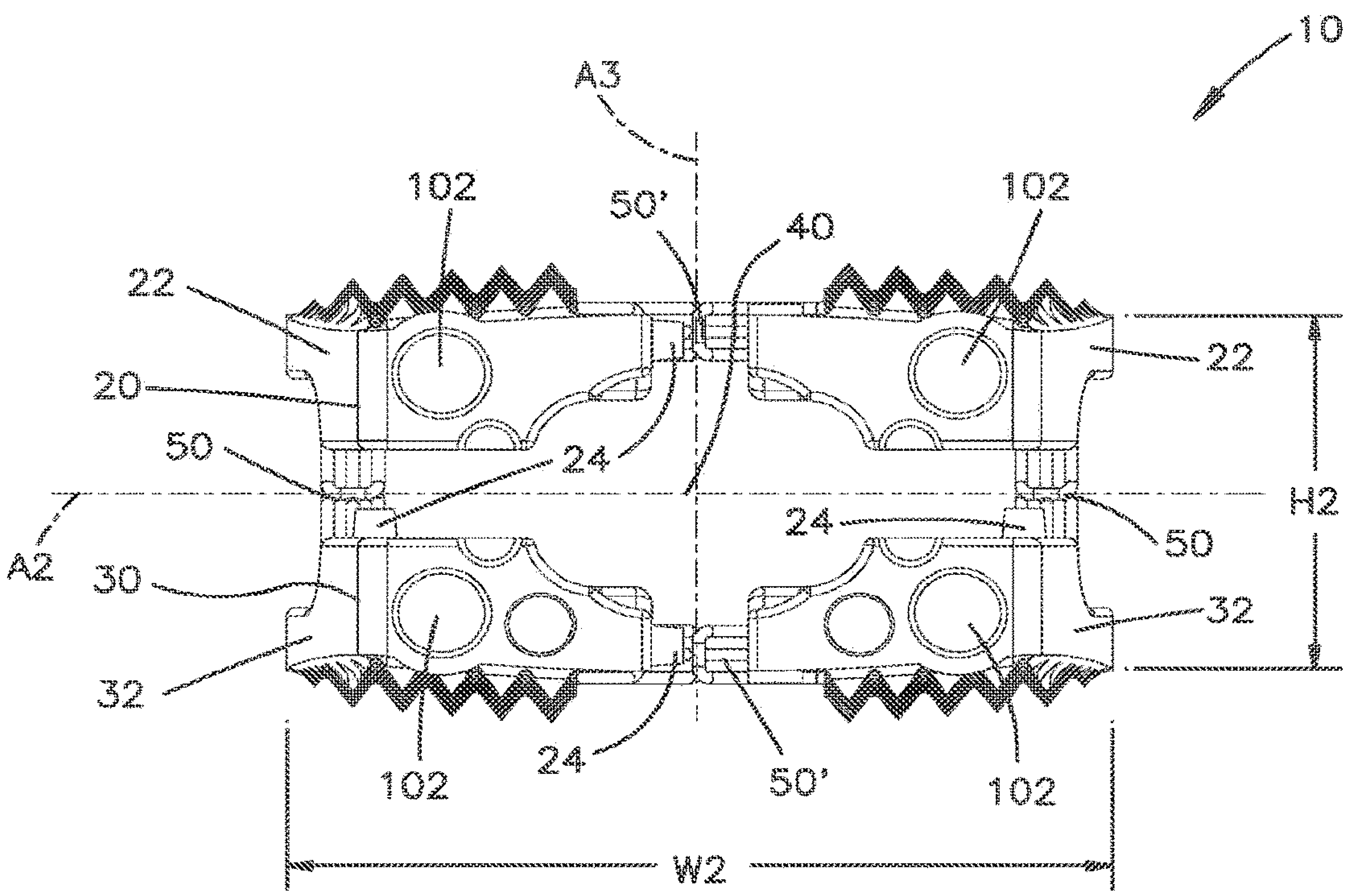
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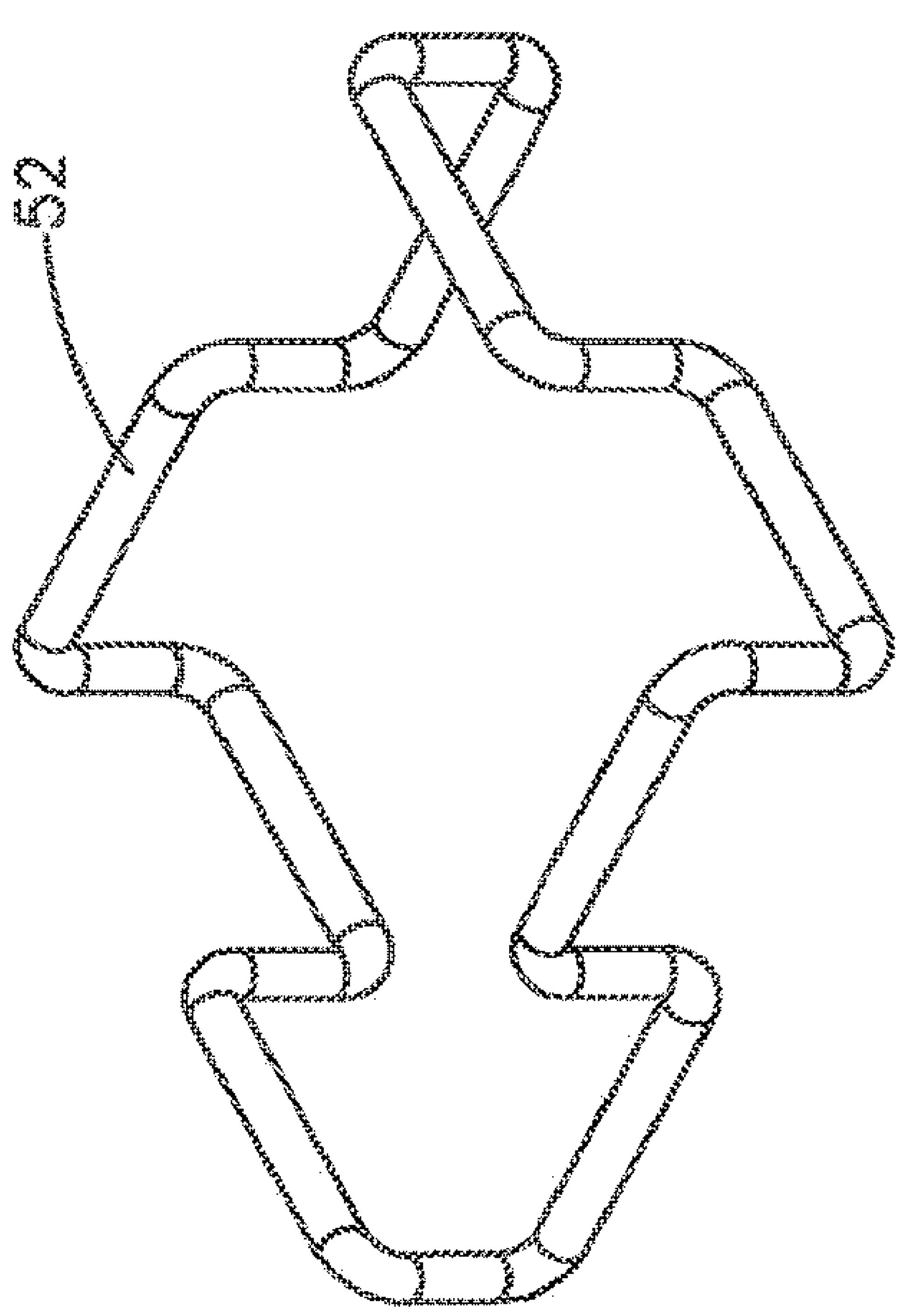
Fig.5B



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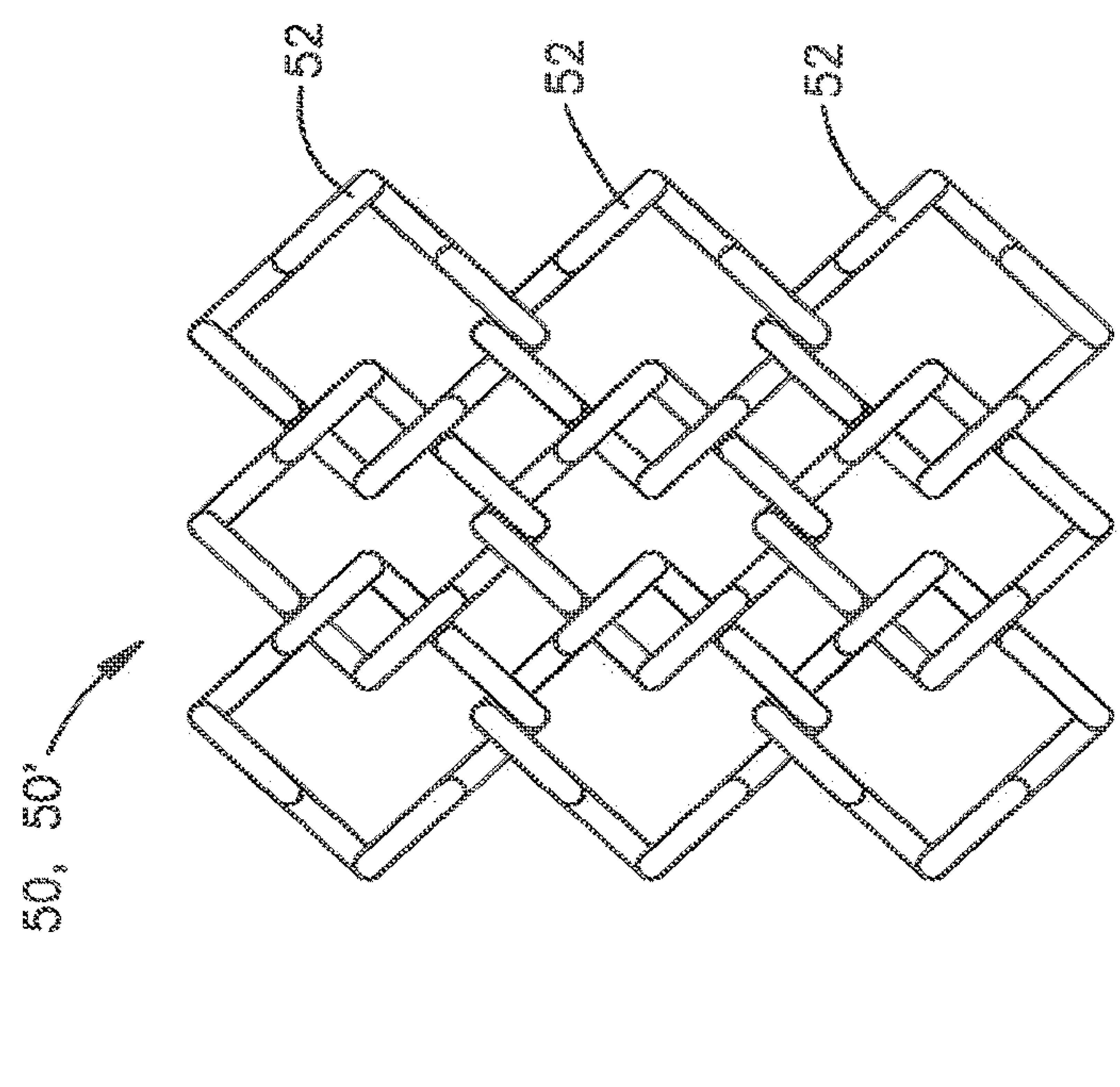

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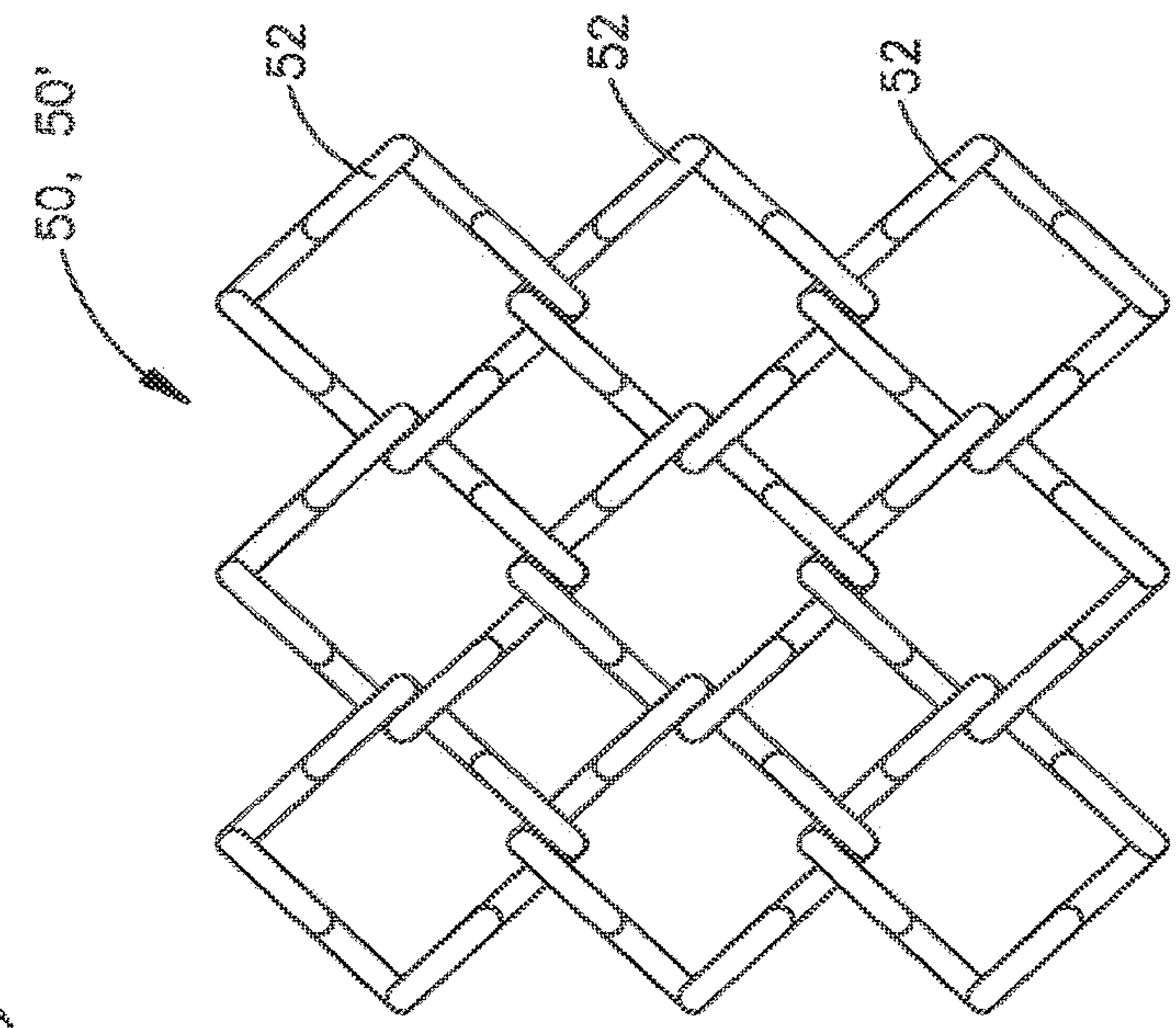

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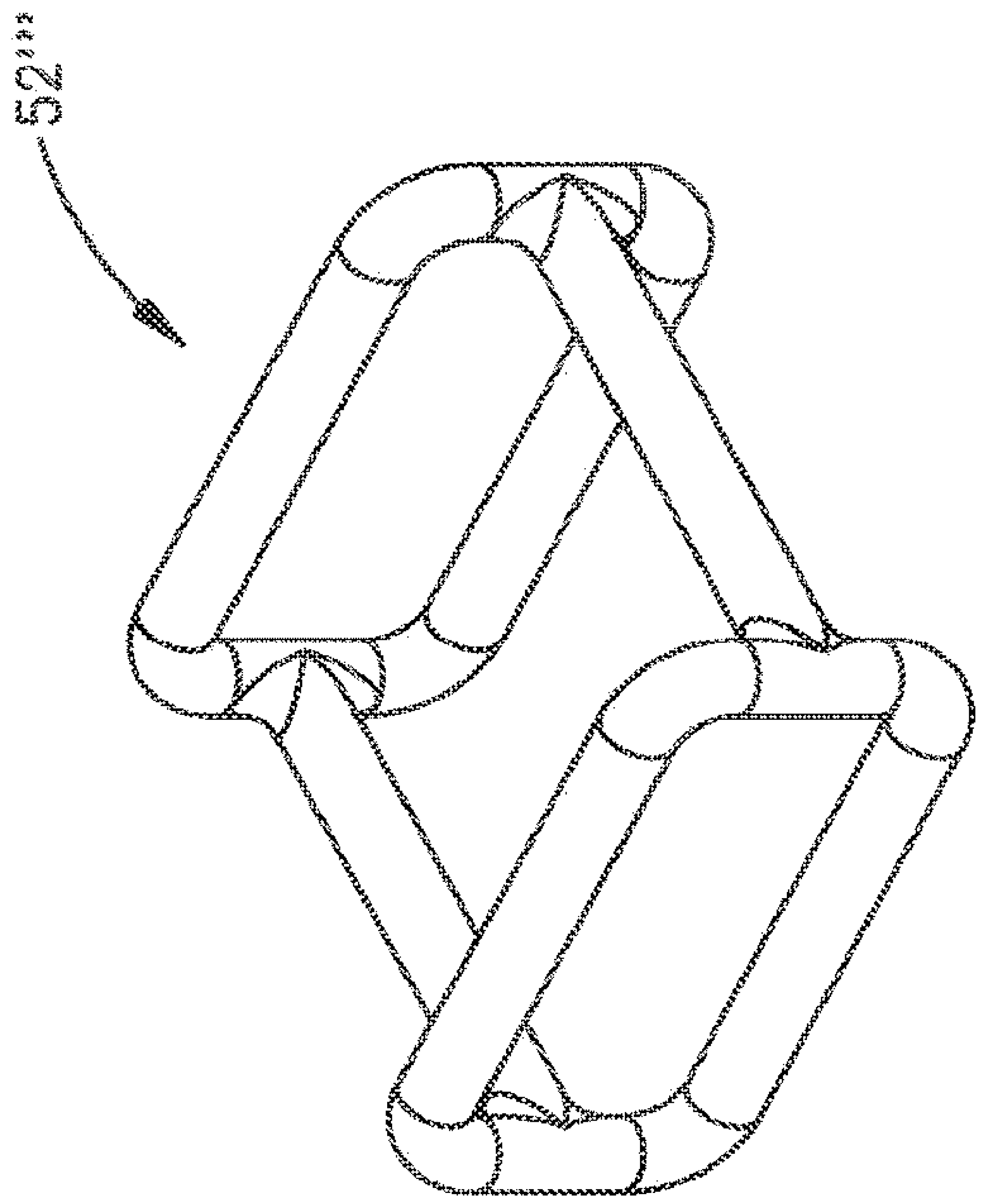

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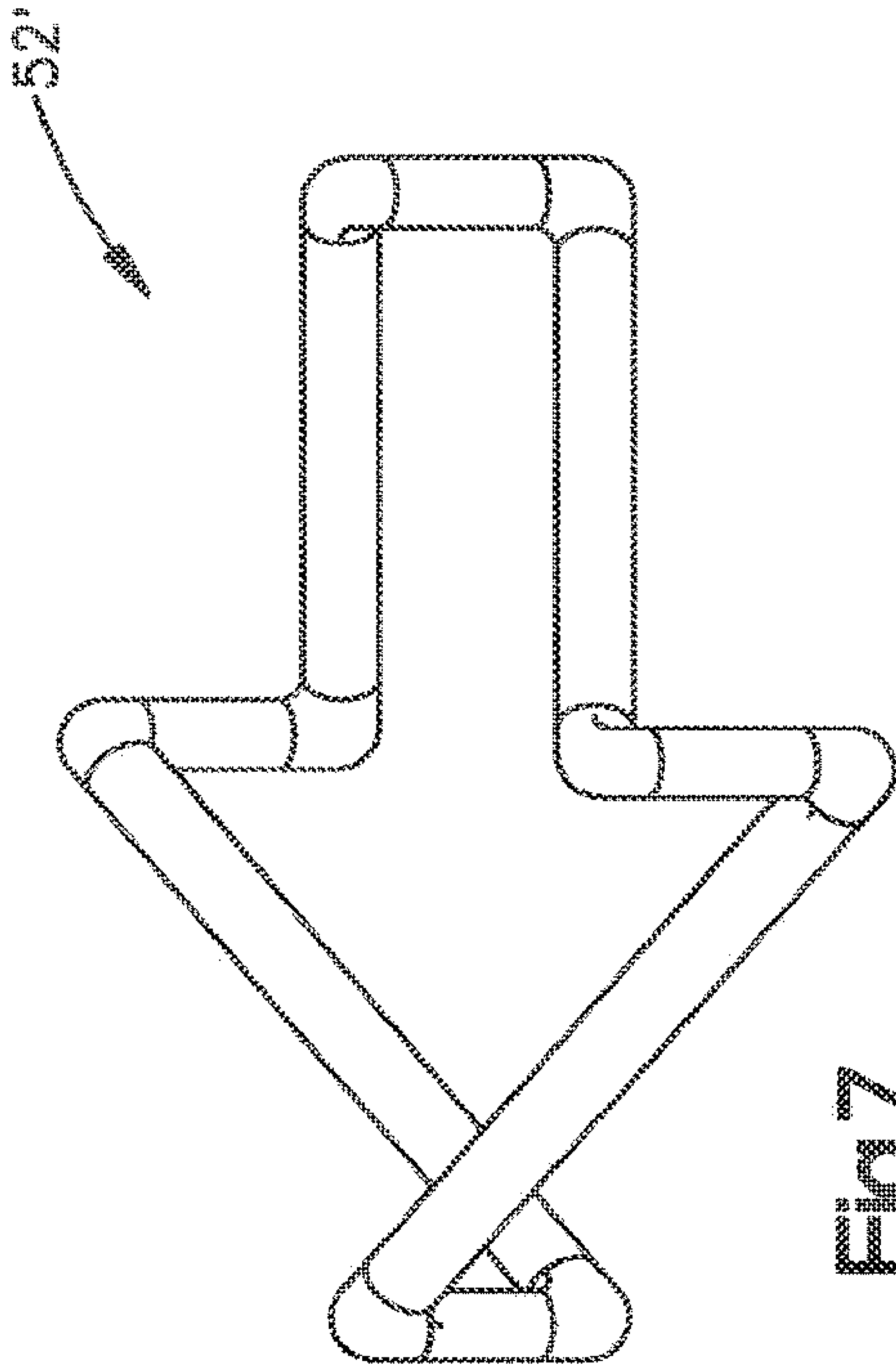

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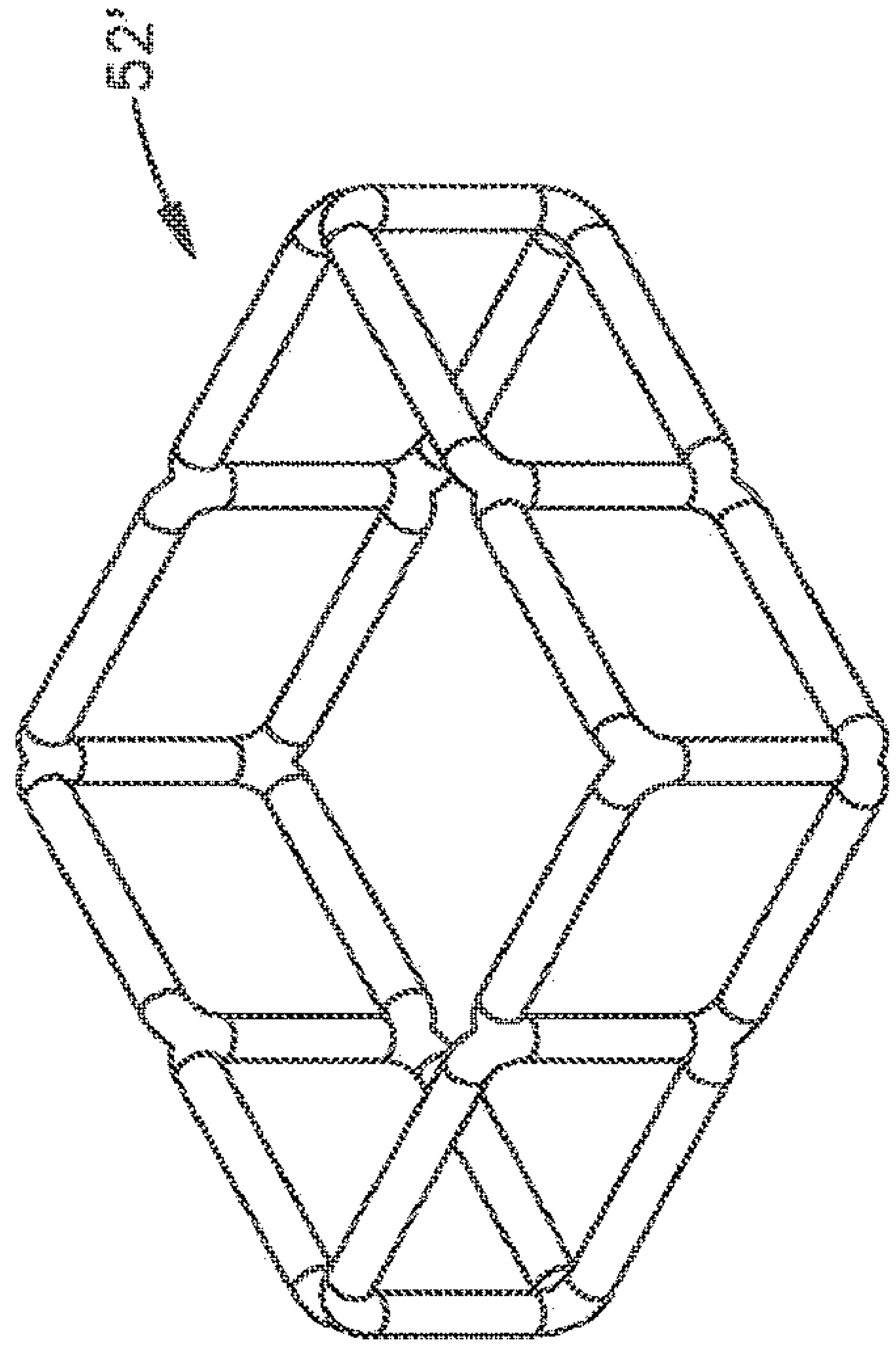

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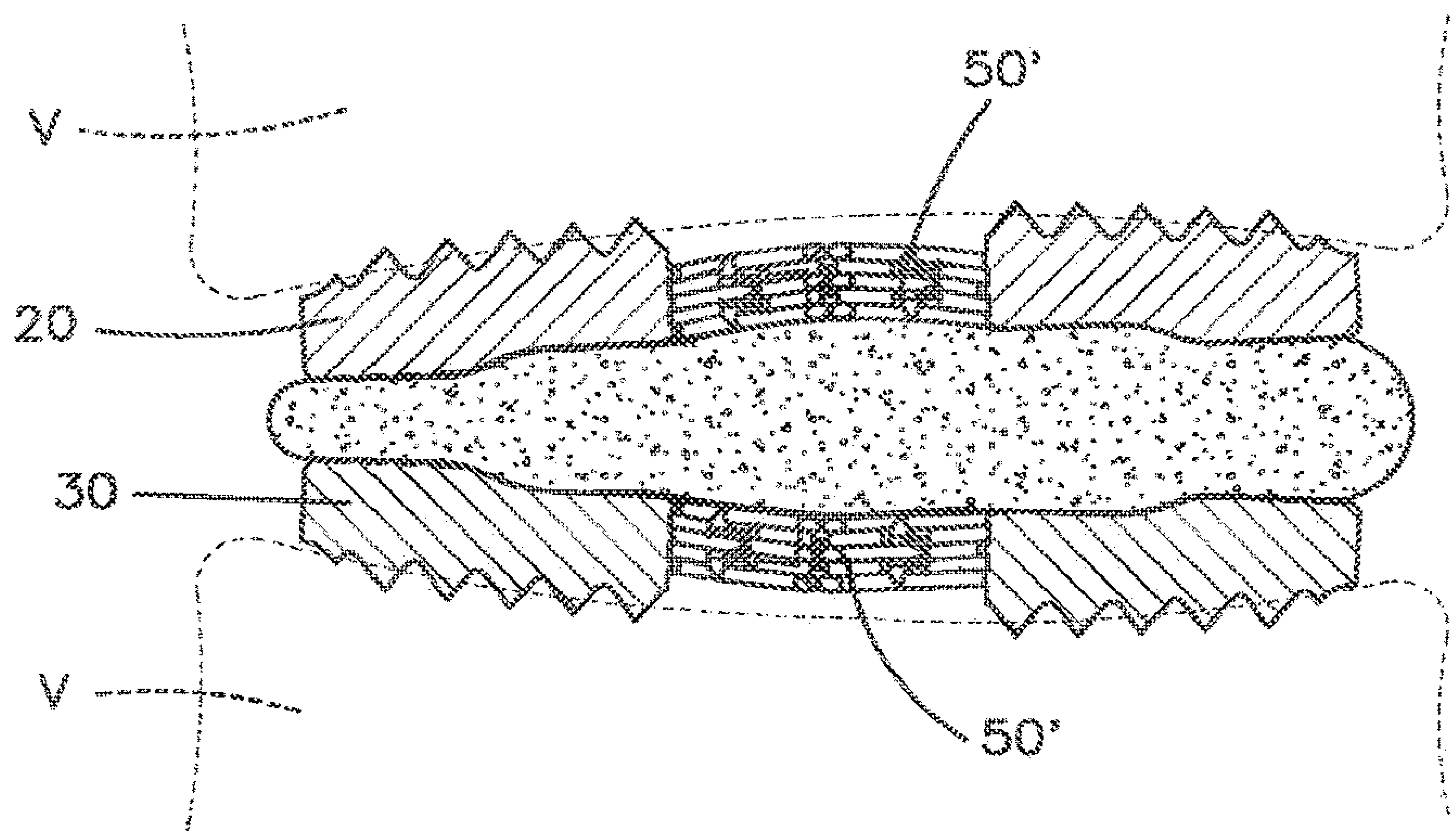

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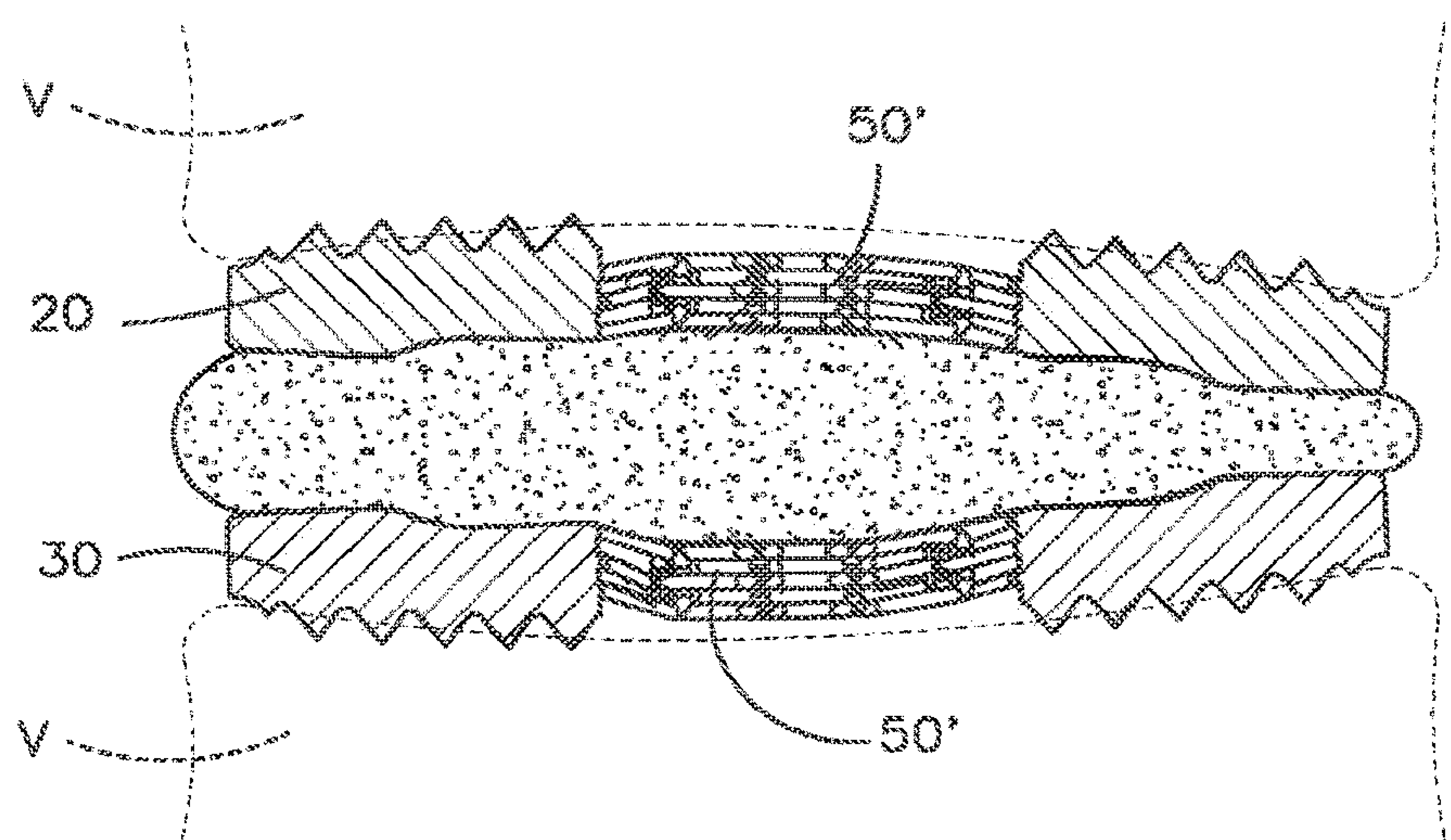

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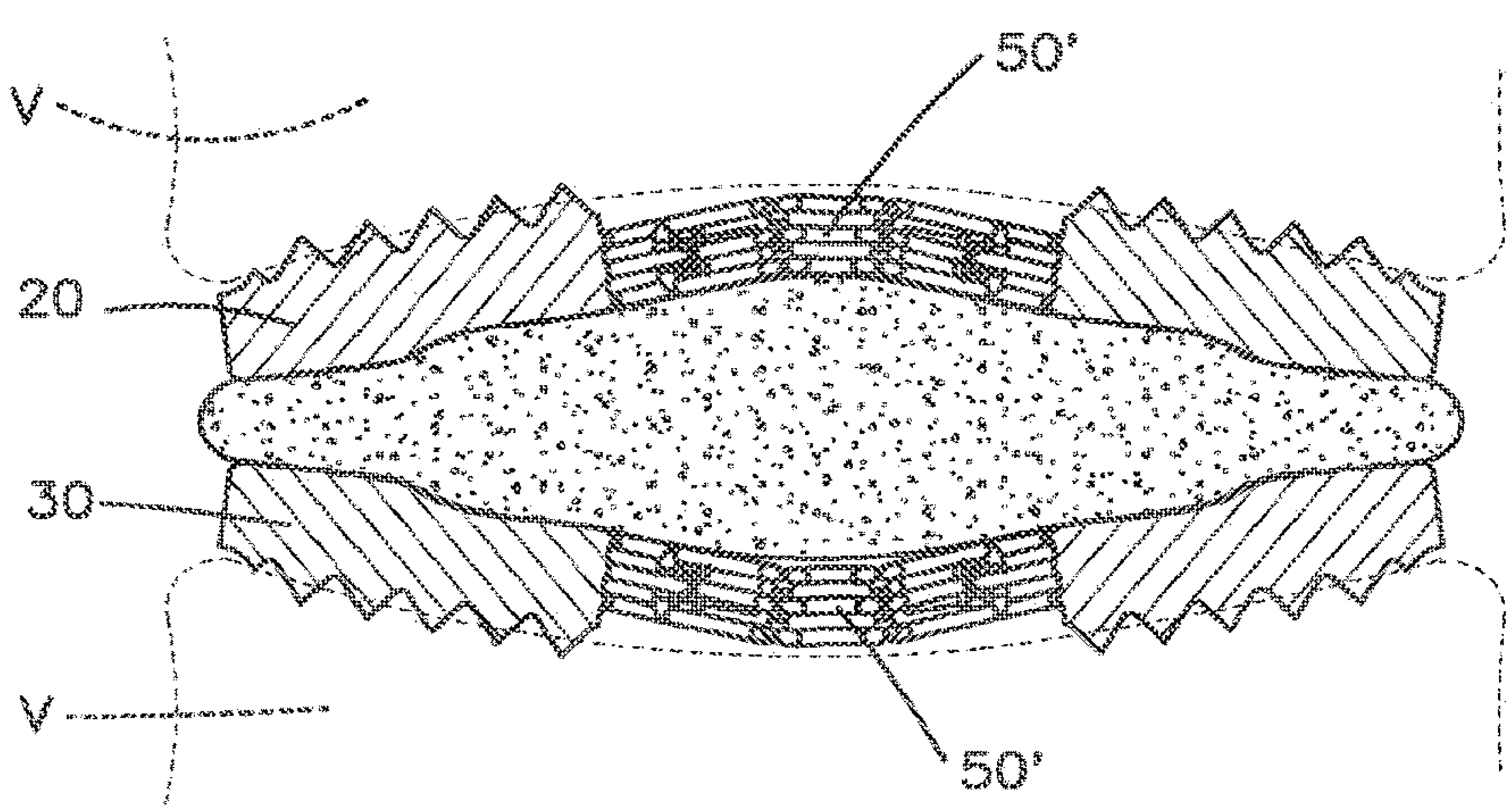

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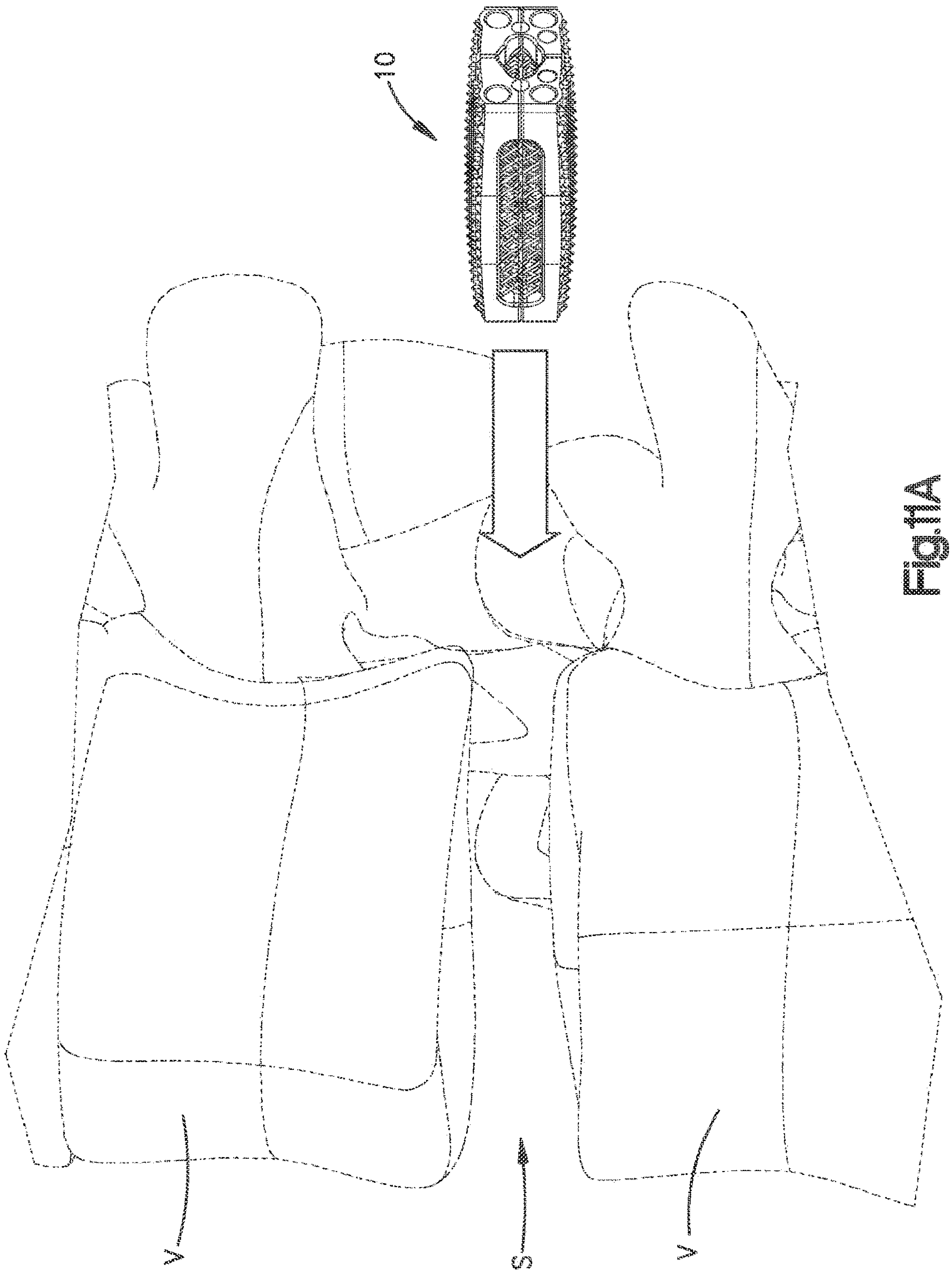

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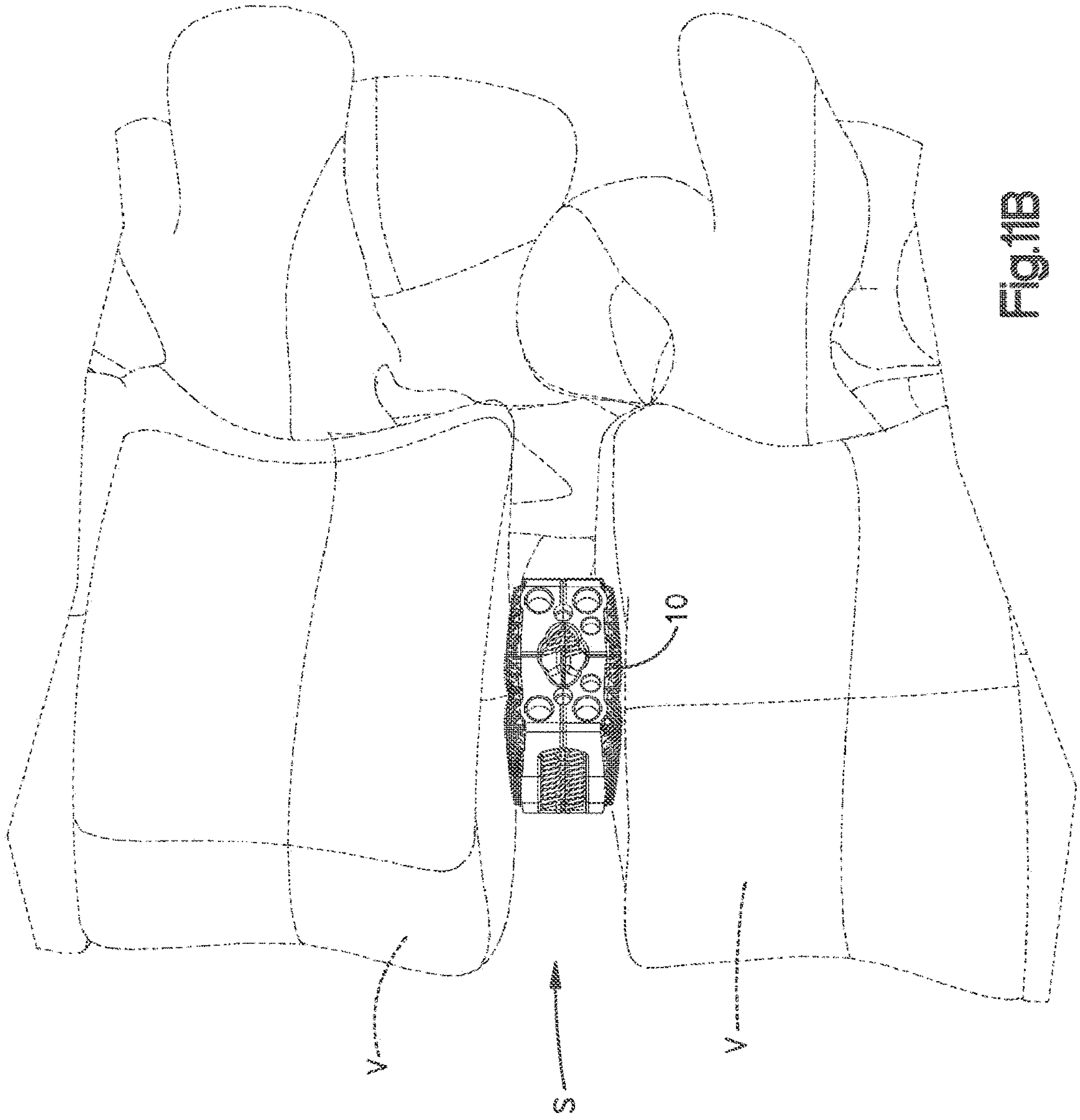

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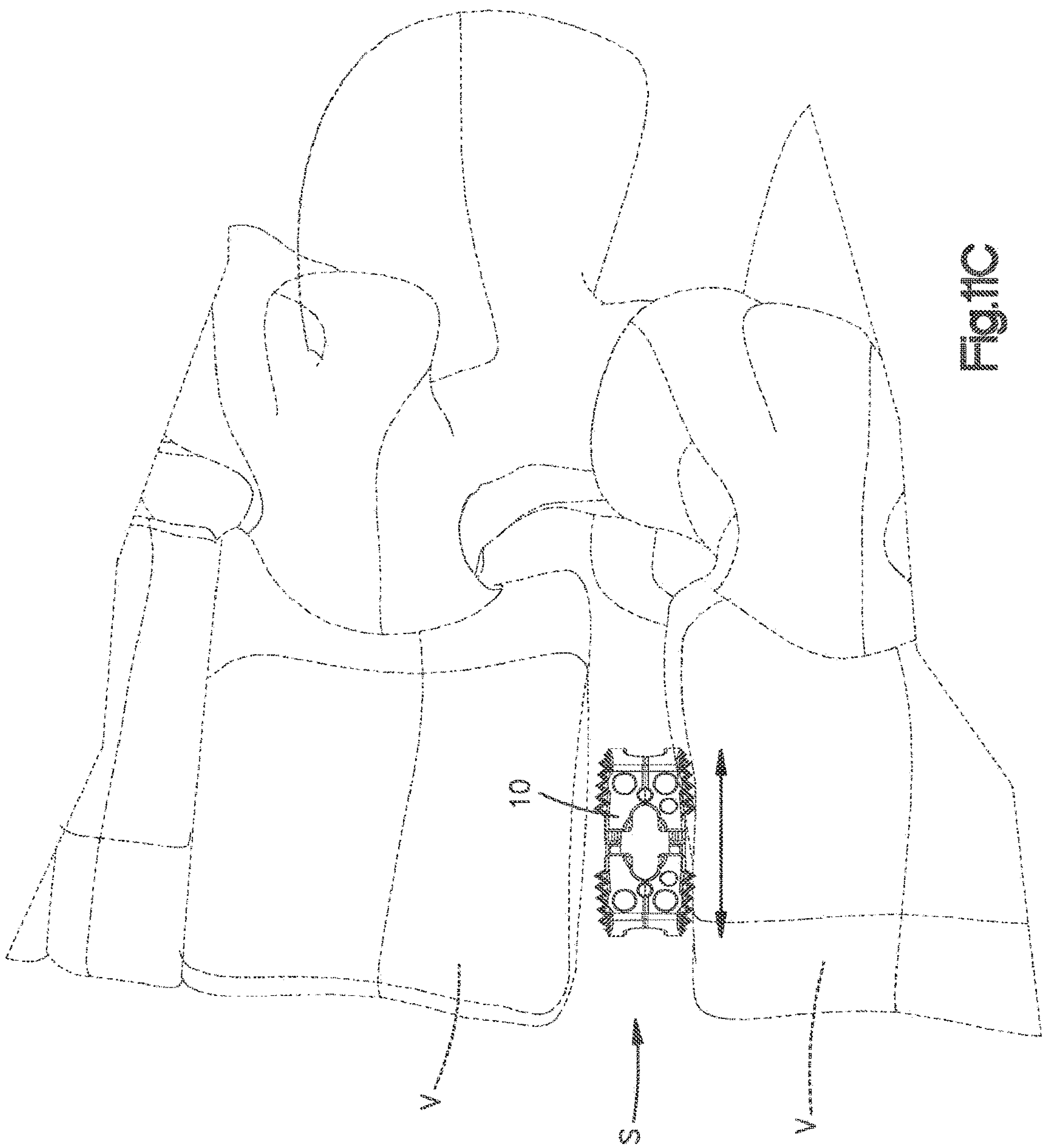

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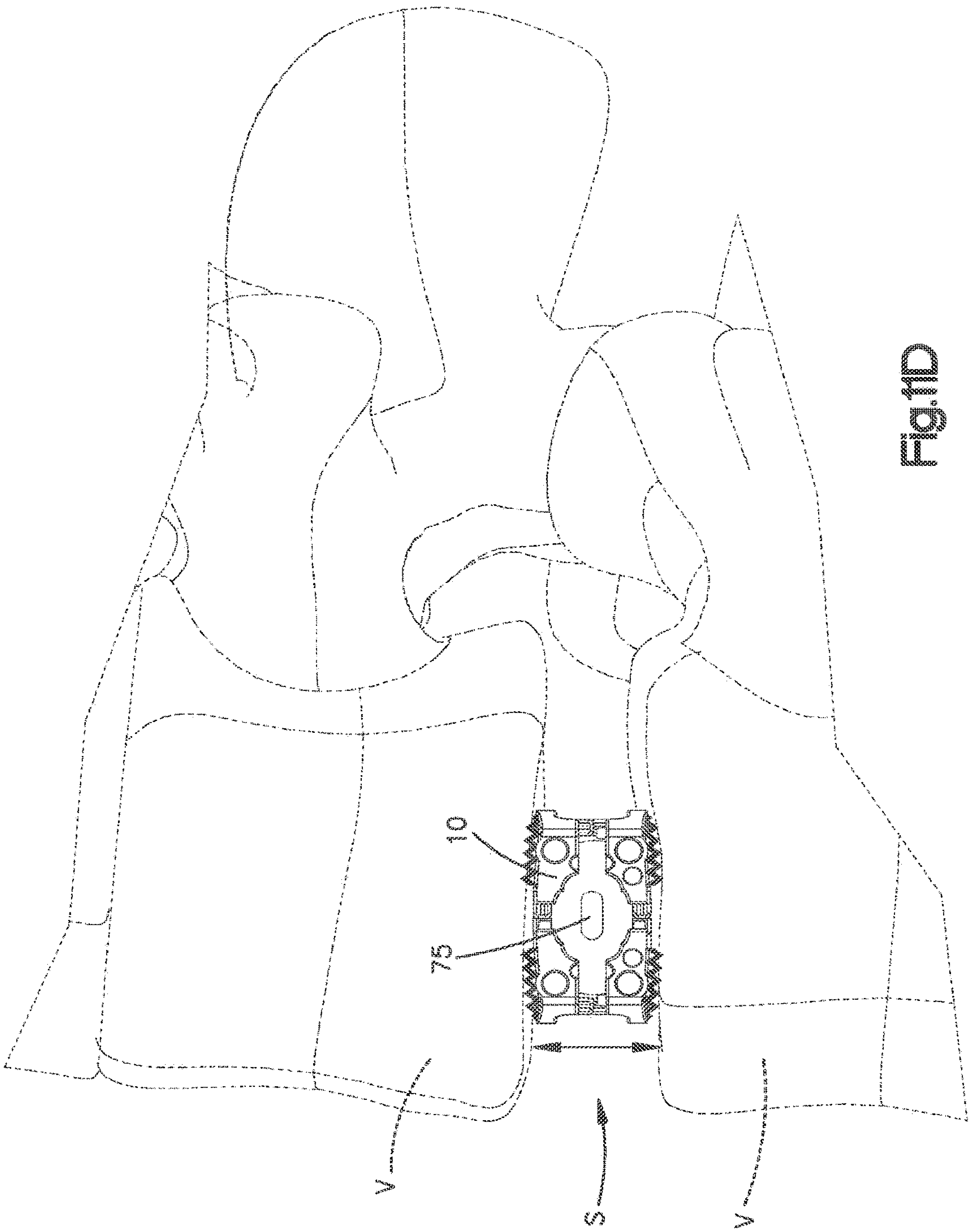

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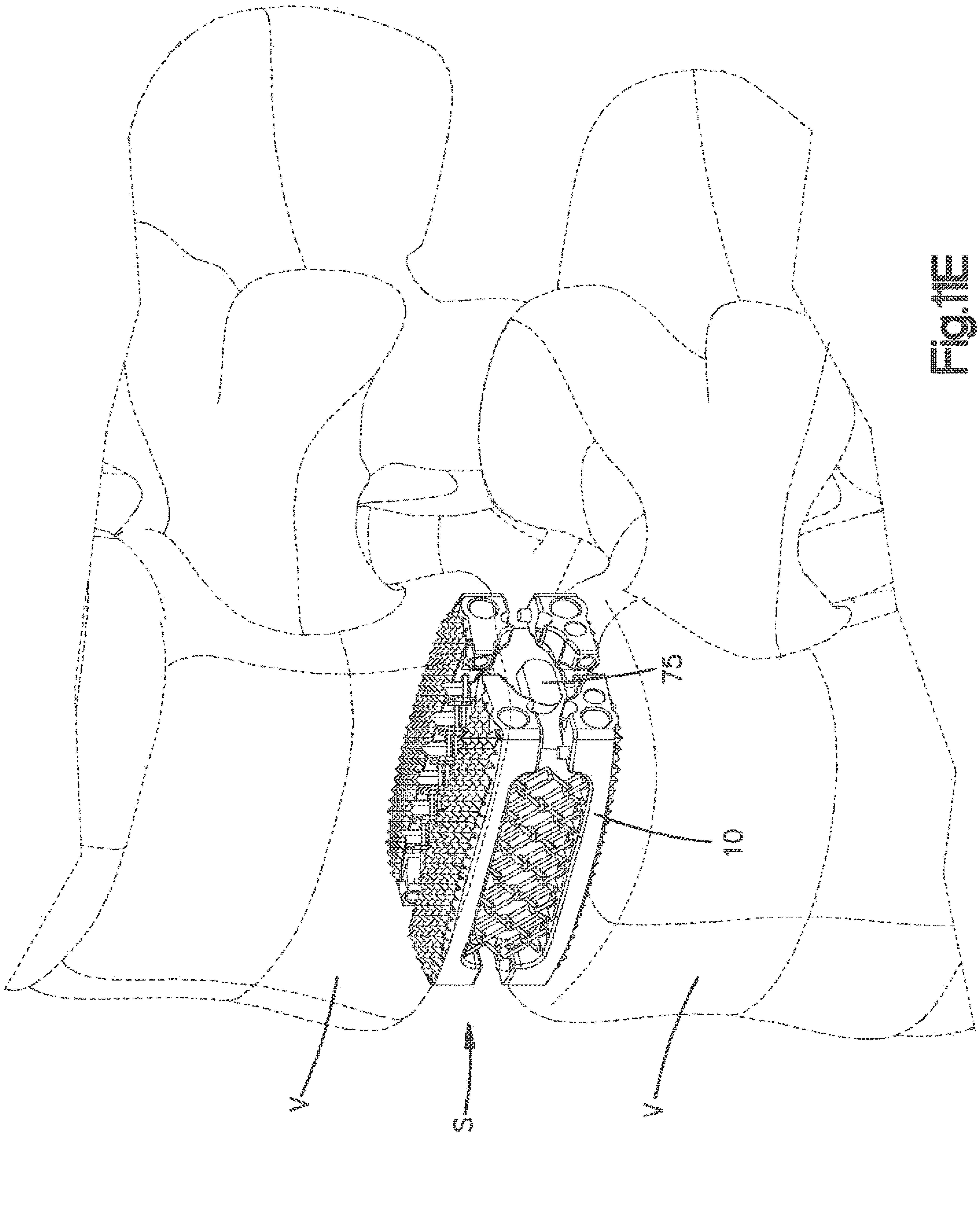

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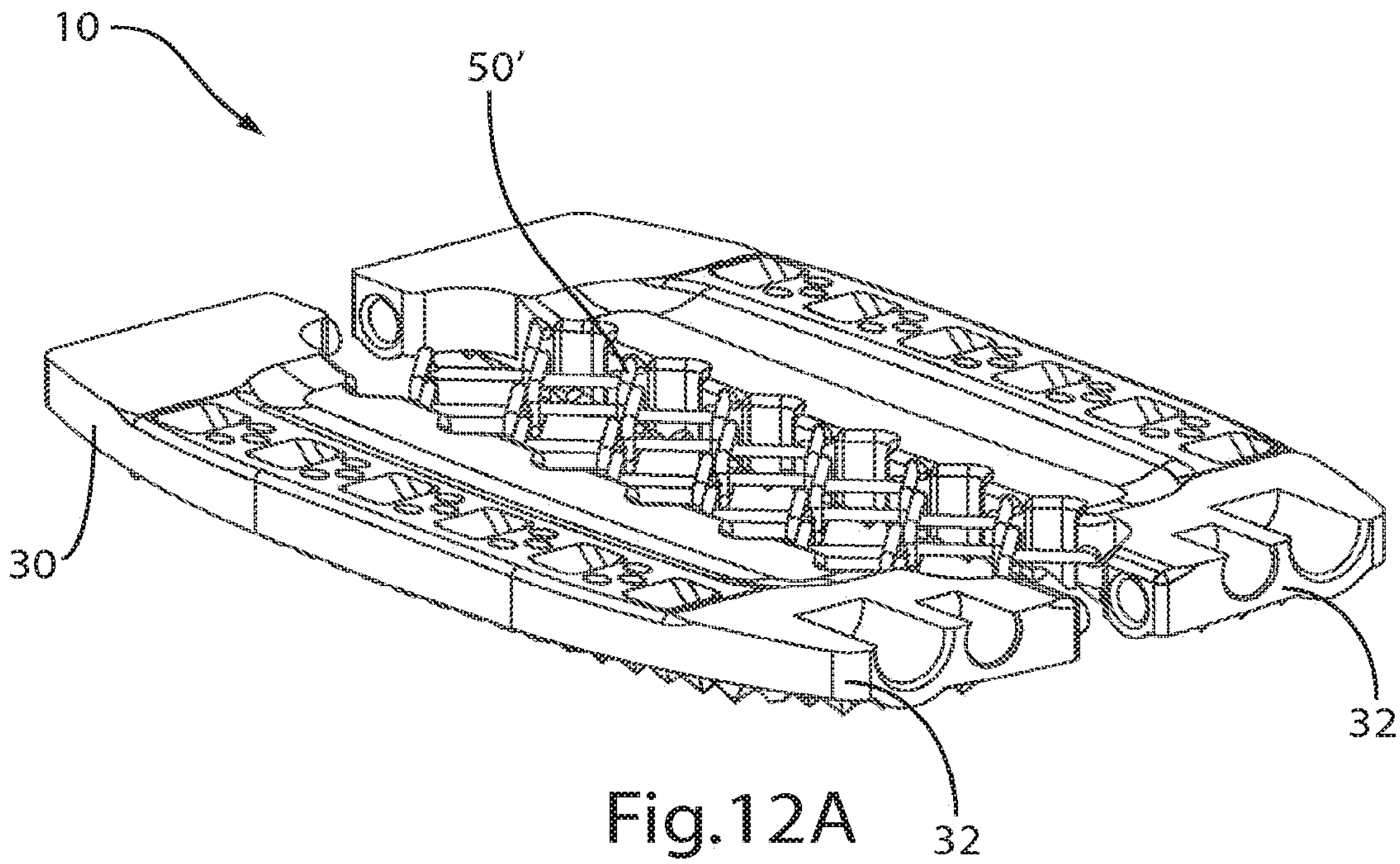

Fig.12A

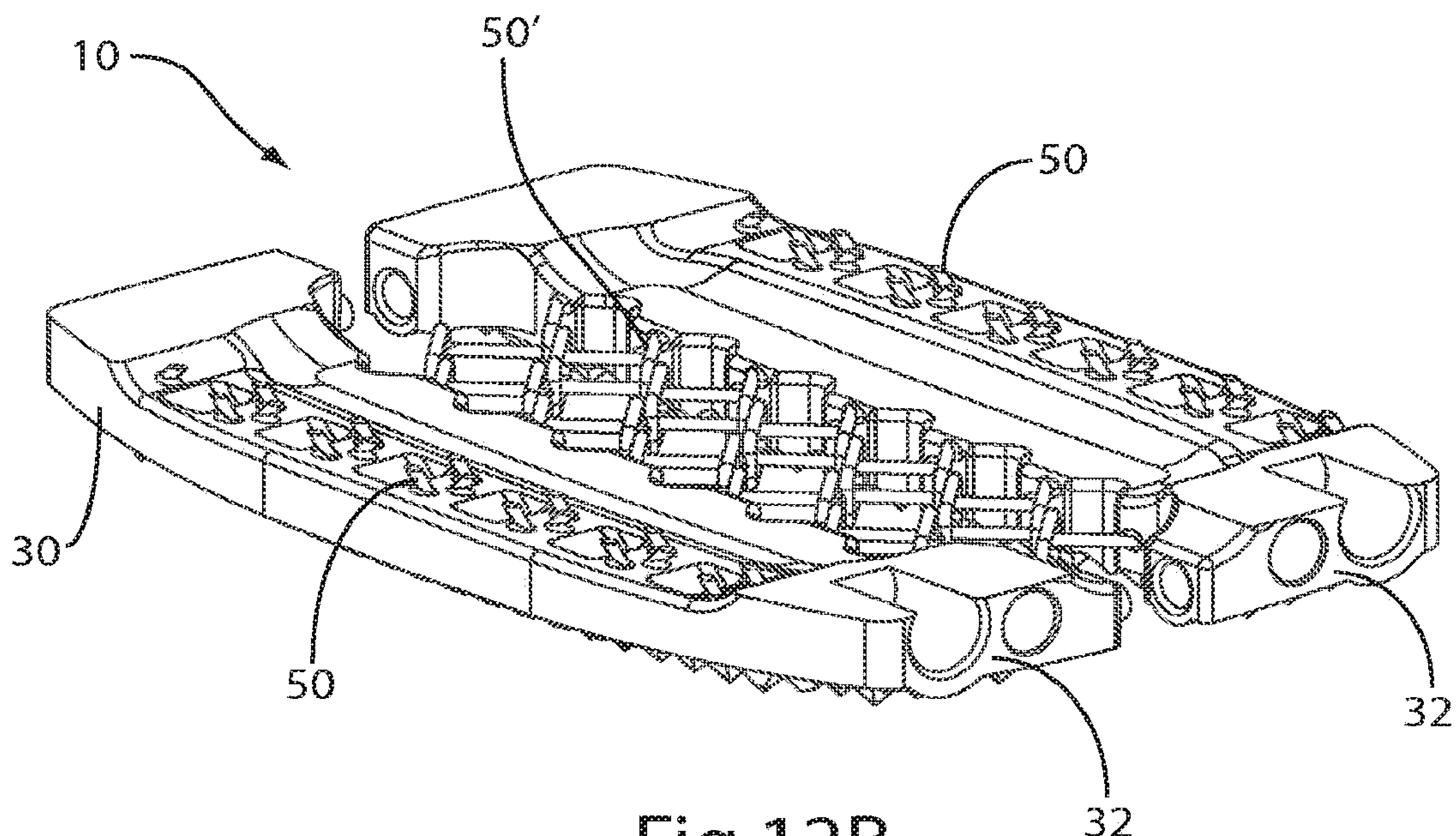

Fig.12B

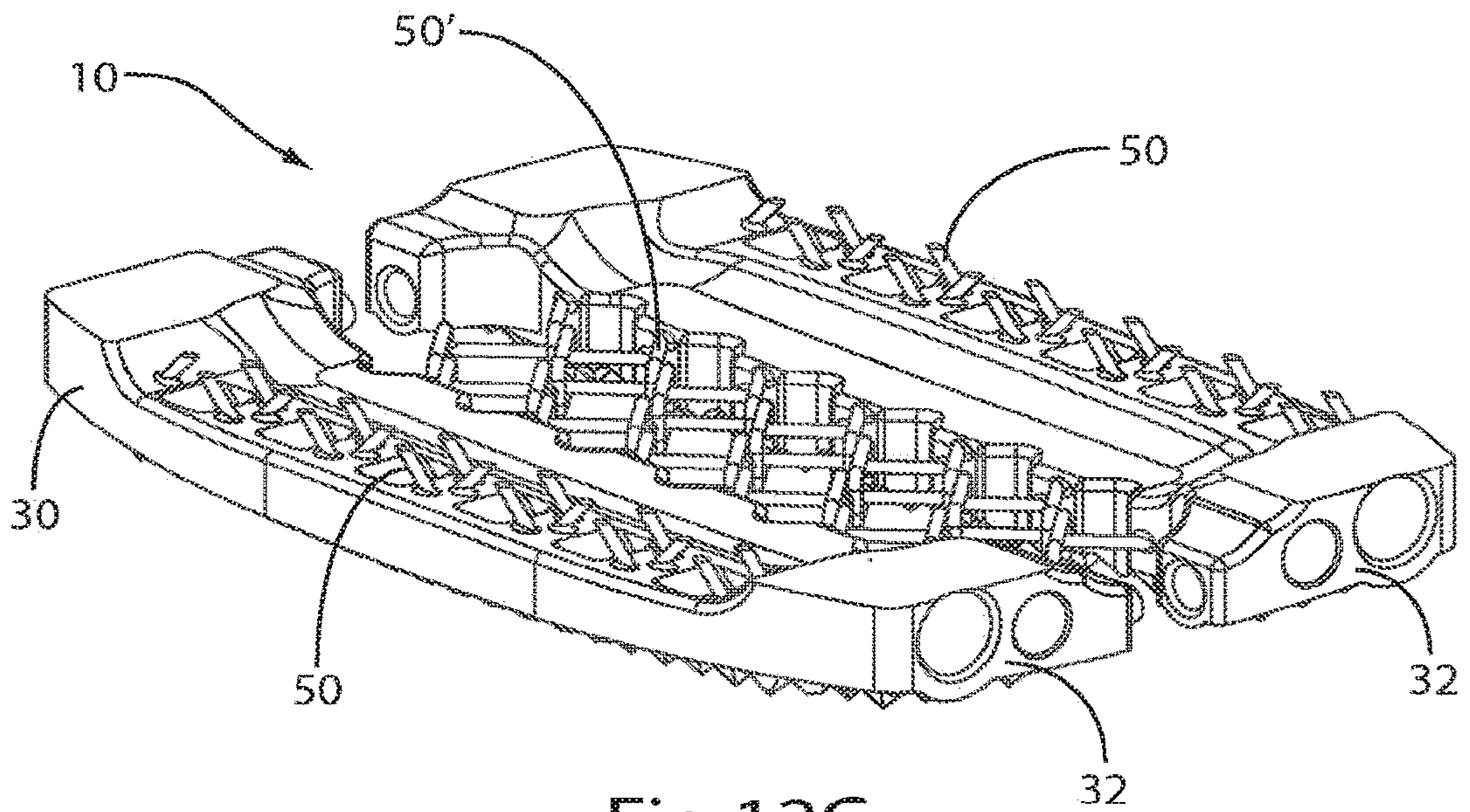

Fig.12C

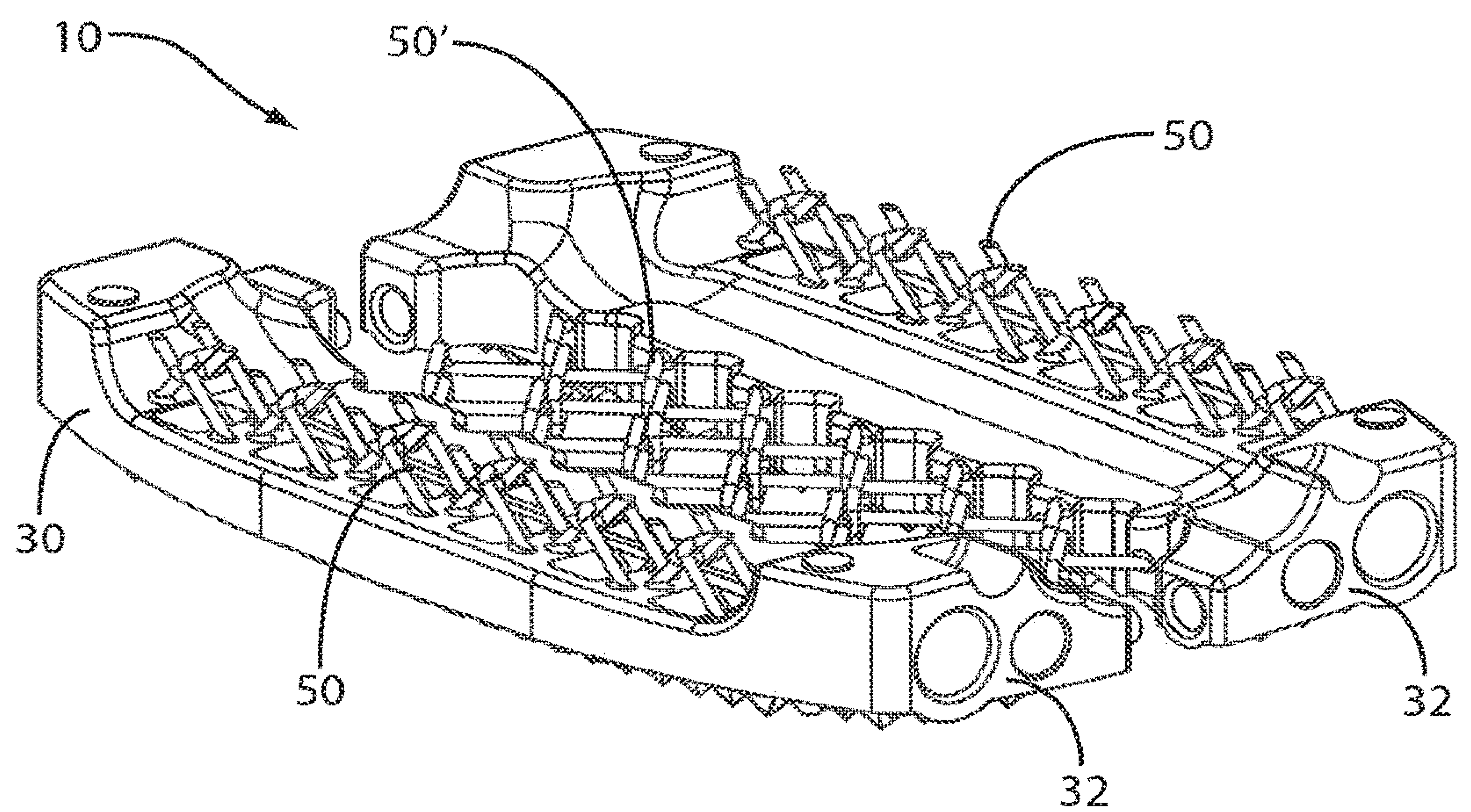

Fig.12D

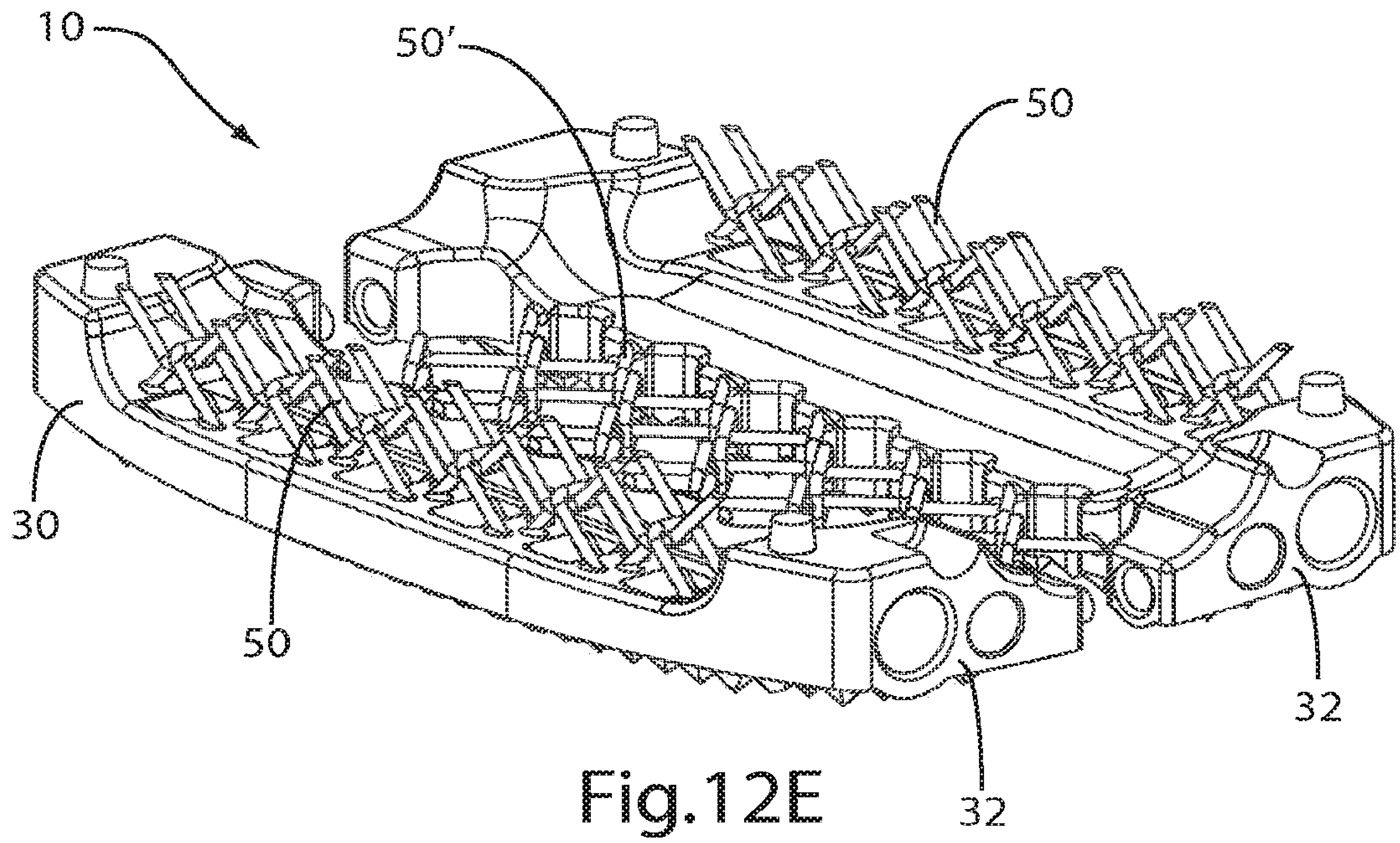

Fig.12E

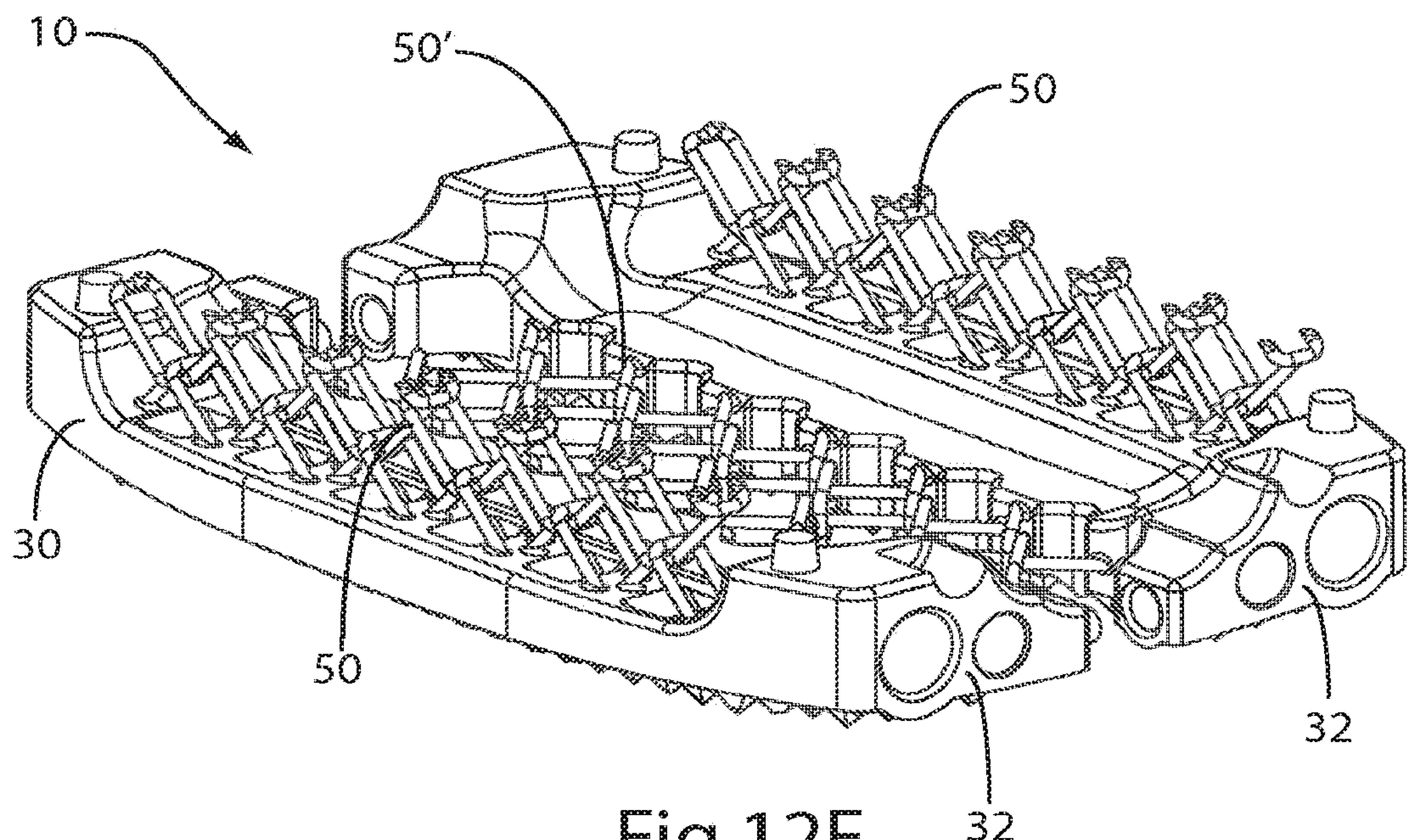

Fig.12F

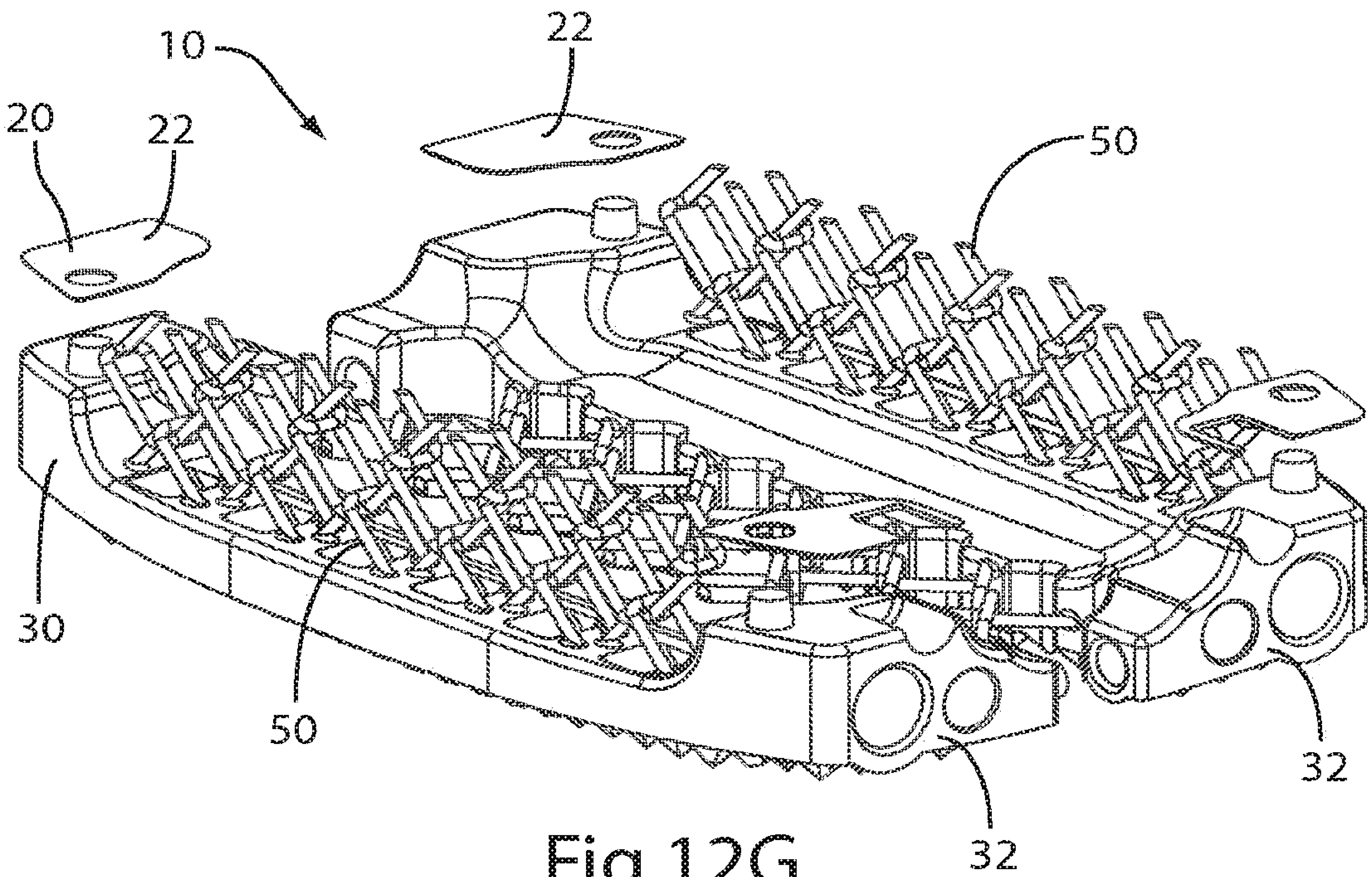

Fig.12G

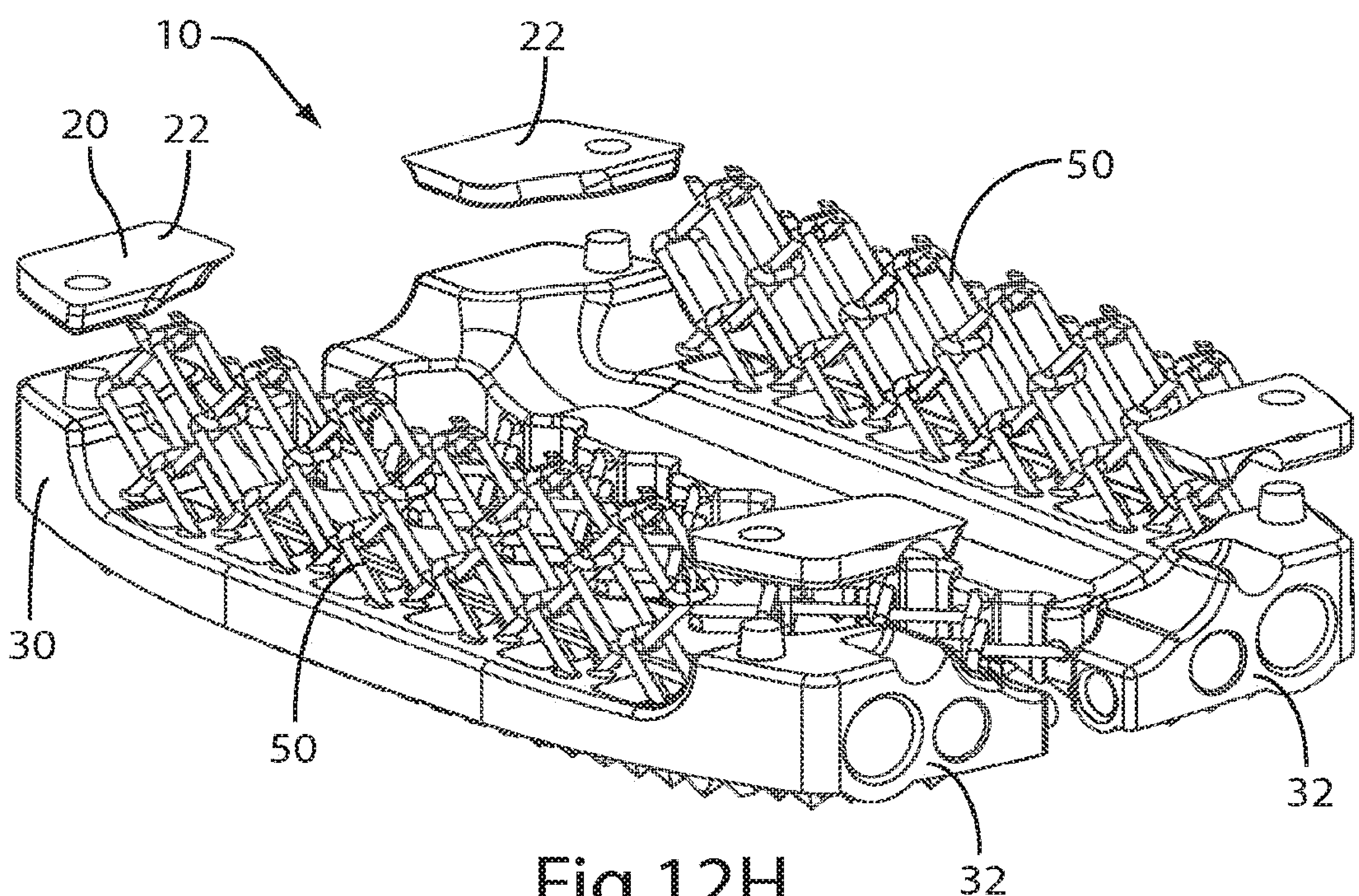

Fig.12H

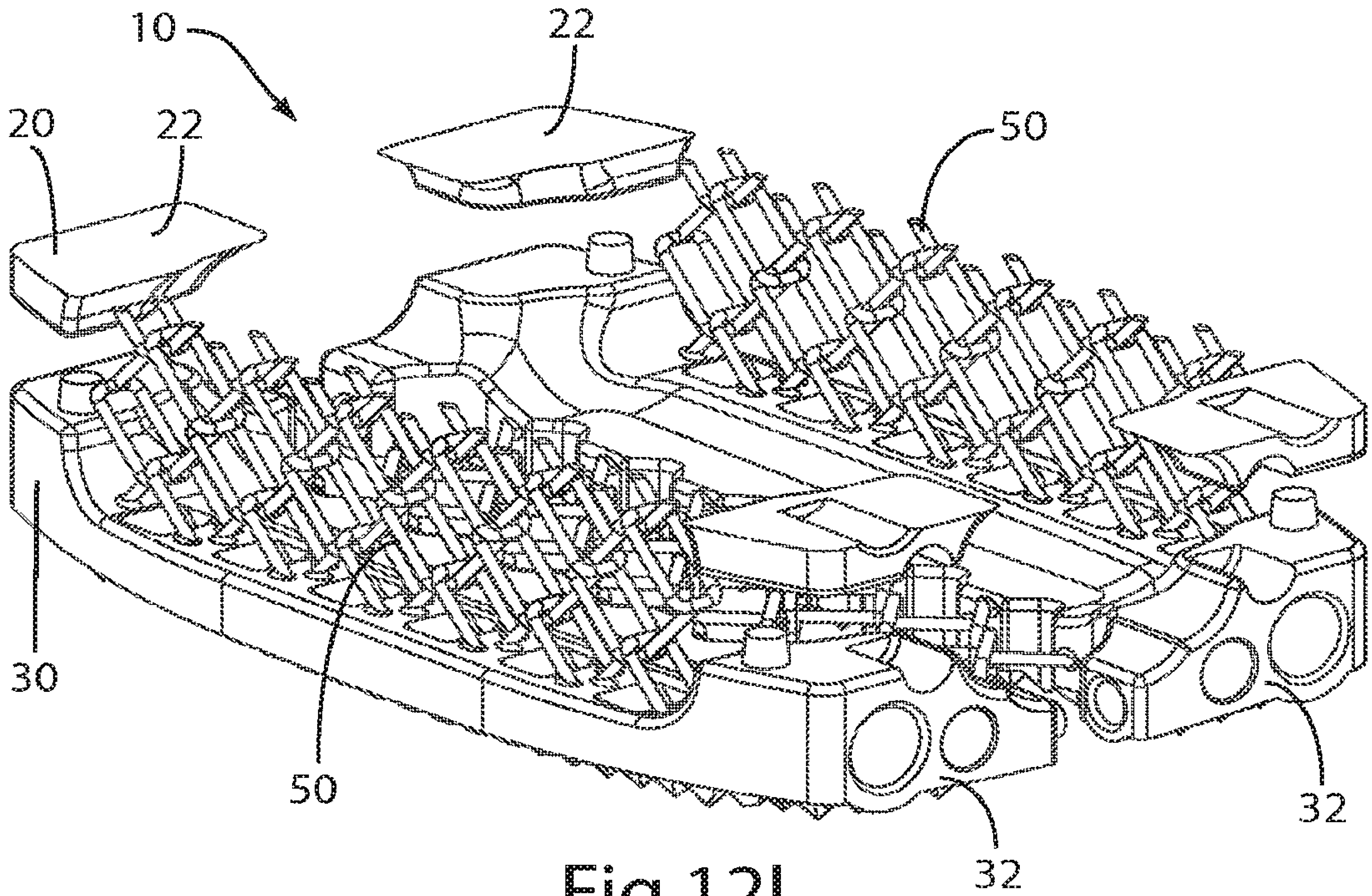

Fig.12I

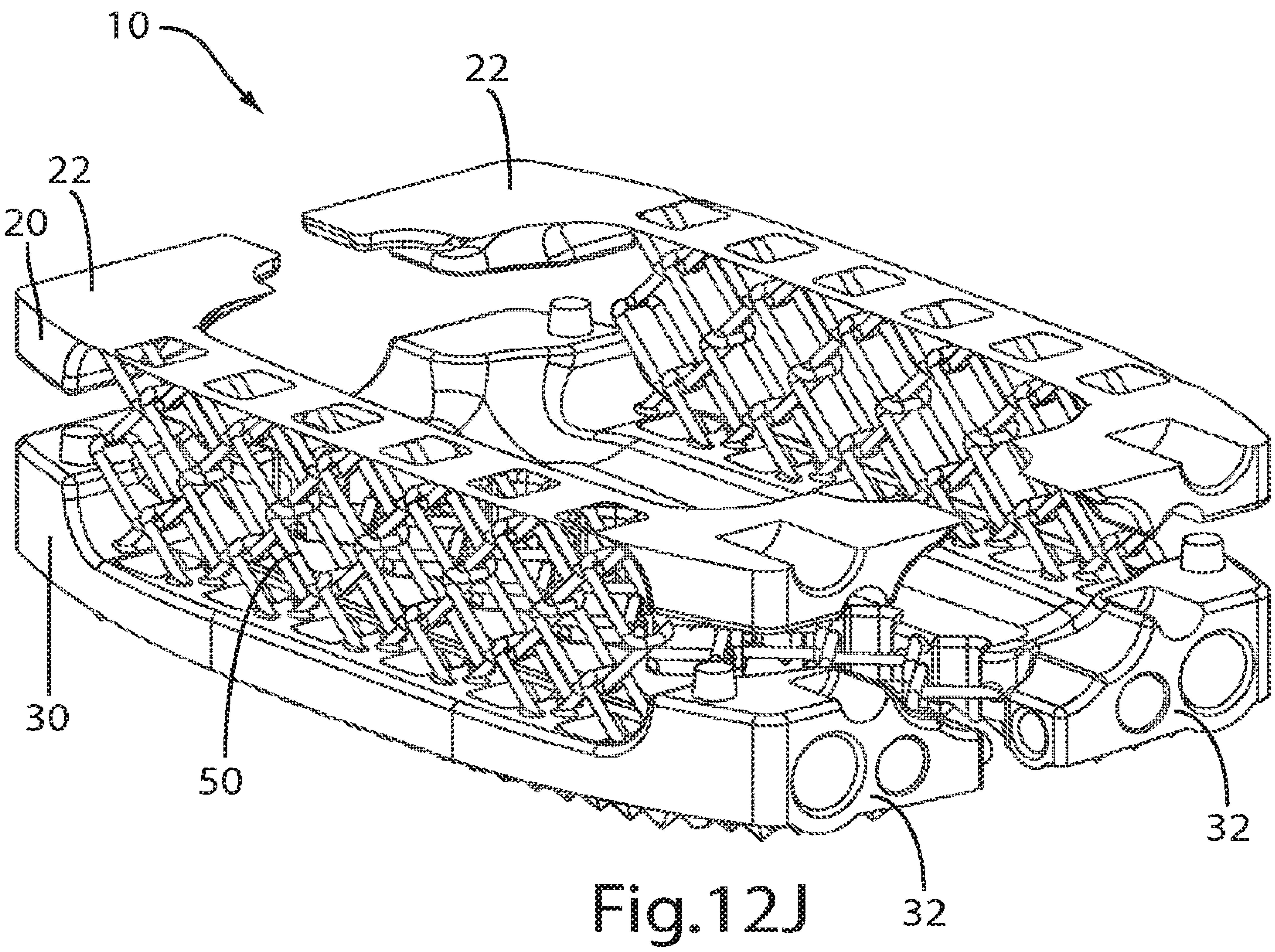

Fig.12J

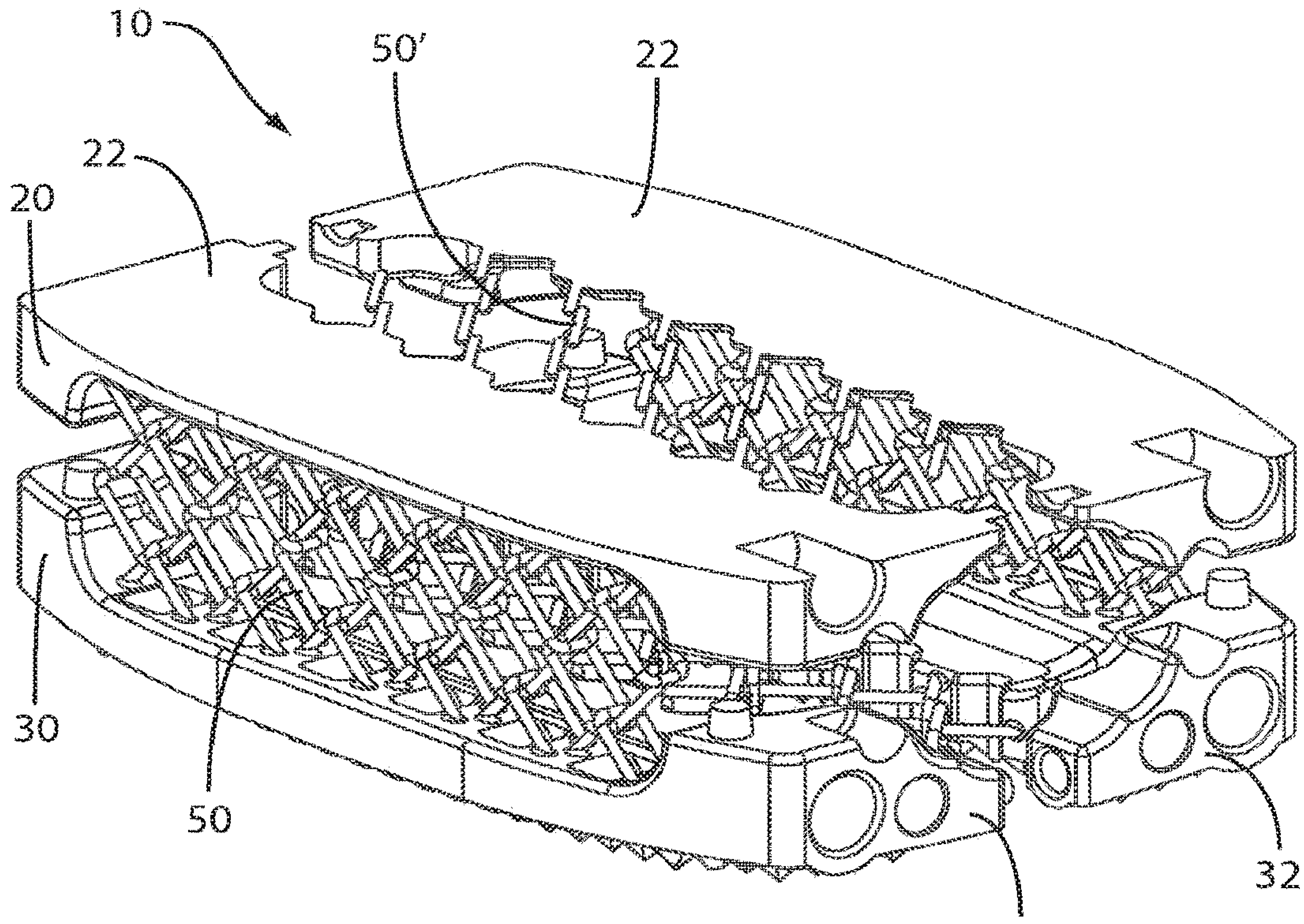

Fig.12K

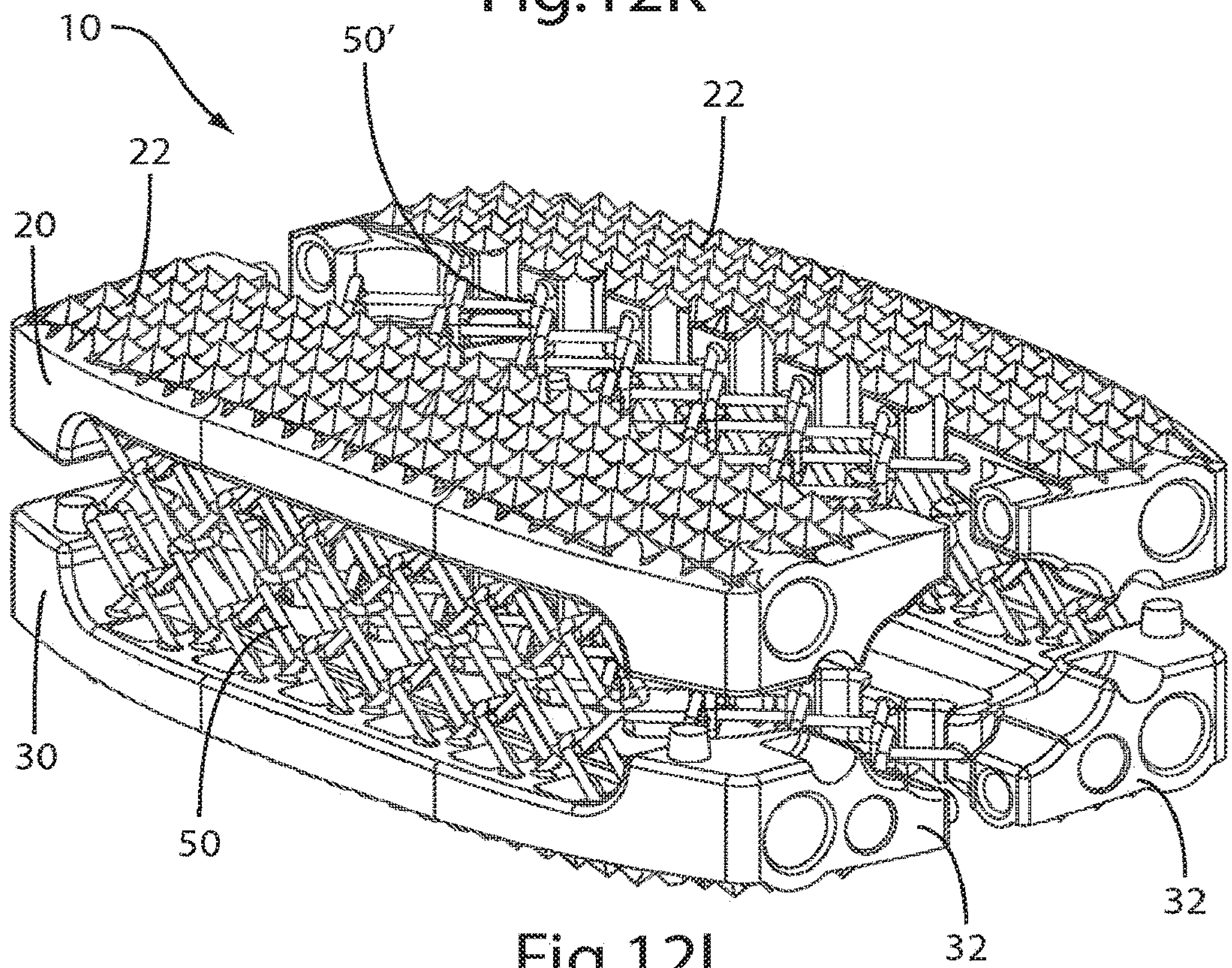

Fig.12L

EXPANDABLE INTERVERTEBRAL IMPLANT AND ASSOCIATED METHOD OF MANUFACTURING THE SAME

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 15/221,169 filed Jul. 27, 2016, which is a continuation of U.S. patent application Ser. No. 14/724,082, filed May 28, 2015, now U.S. Pat. No. 9,433,510, which is a continuation of U.S. patent application Ser. No. 14/032,231, filed Sep. 20, 2013, now U.S. Pat. No. 9,295,562, issued Mar. 29, 2016, which is a continuation of U.S. patent application Ser. No. 12/812,146, filed Jul. 8, 2010, now U.S. Pat. No. 8,551,173, issued Oct. 8, 2013, which is a national stage application under 35 U.S.C. § 371 of International Application No. PCT/US2009/031567, filed on Jan. 21, 2009, which claims the benefit of U.S. Provisional Application No. 61/021,778, filed on Jan. 17, 2008. The entire content of each aforementioned application is incorporated by reference herein for all purposes.

BACKGROUND

People, especially elderly people, may suffer from osteoporosis. One aspect of osteoporosis may be the partial or complete collapse of the bony structure of the spine, which in turn can cause loss of vertebral height, fracture of a vertebral disc, facet and nerve impingement, etc. Collapse of the spine often results in, for example, pain, reduction of lung function, unbalanced stature, etc. One treatment option may be a surgical procedure to re-align the vertebra (e.g., to re-establish balanced curvature of the spine as well as the intervertebral disc space).

Re-alignment of a spine including a damaged vertebra or disc may be accomplished by replacing the damaged vertebra, disc or portions thereof with an intervertebral implant. That is, an intervertebral implant may be inserted into the intervertebral disc space of two neighboring vertebral bodies or into the space created by removal of portions of or the entire vertebral body after removal of damaged portions of the spine. Preferably, the intervertebral implant restores the spine, as much as possible, to a natural state, i.e. to restore the original height of the intervertebral disc or the series of vertebra and, thus, the original distance between the two neighboring or adjacent vertebral bodies or vertebral bodies in various levels of the spine.

Typically implantation of one or more intervertebral implants is not part of a treatment procedure for osteoporosis. One reason for this may be that intervertebral implants are often designed with high structural stiffness. Osteoporotic bone is usually brittle, thus increasing the risk of breaking a vertebral endplate during a surgery or implantation of an implant and the endplates may have a uneven surface. For example, a stiff implant may impact a point or small area of an uneven surface of the osteoporotic bone, thereby creating a stress concentration and potentially damaging the bone. Therefore, the incorporation of an intervertebral implant in certain cases, is contra-indicated for patients with osteoporotic bone. Another reason for not incorporating an intervertebral implant may be that the insertion approach for implanting an intervertebral implant is difficult and risky, especially in elderly patients.

Alternatively, rather than implanting an intervertebral implant, a surgeon may elect to perform a Vertebralplasty and/or Cavitoplasty procedure on the patient's spine. In an

exemplary method of performing a Vertebralplasty and/or Cavitoplasty procedure, a protective sleeve or cannula may be inserted into the patient's body, adjacent to the patient's spine. The spine may then be re-aligned if fractured or re-fractured. Next cement is inserted into the spine to replace lost bone and/or to limit future cracks. After the hardening of the cement, the treated section of the spine may be re-aligned and the patient may then return to his or her daily activity. In a Cavitoplasty procedure, a cavity may be formed in one or more of the vertebral bodies for receiving a portion of the cement.

It would be desirable to construct an intervertebral implant that is relatively simple to insert into a patient's spine at a relatively small size and which is able to expand to restore the original height of the removed spinal material or to a height desired by a surgeon. It would also be desirable to construct an intervertebral implant that is adaptable to uneven surfaces of an osteoporotic vertebral bone to limit stress concentrations when the implant is expanded and contacts or applies pressure to a patient's endplate.

SUMMARY

The present invention relates to an expandable intervertebral implant. More particularly, a preferred embodiment of the present invention relates to an intervertebral implant that is laterally and vertically expandable in situ from a collapsed, non-expanded or first insertion configuration to a second expanded configuration. The expandable intervertebral implant preferably includes superior and inferior bone contacting members connected together via one or more expandable components such as, for example, a wire netting so that the implant is vertically expandable in the cranio/caudal direction. The superior and inferior bone contacting members preferably are formed by two or more bone contacting components connected together via one or more expandable components such as, for example, a wire netting so that the implant is laterally expandable in the lateral direction if implanted via an anterior approach or laterally expandable in the anterior-posterior direction if implanted via a lateral approach.

The present invention also relates to an associated method of inserting and sequentially expanding the intervertebral implant and an associated method of manufacturing the intervertebral implant such that the intervertebral implant can be manufactured as an integral component.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary, as well as the following detailed description of the preferred embodiments of the application, will be better understood when read in conjunction with the appended drawings. For the purposes of illustrating the expandable intervertebral implant, surgical method for implanting the intervertebral implant and manufacturing method for forming the intervertebral implant of the present application, there are shown in the drawings preferred embodiments. It should be understood, however, that the application is not limited to the precise arrangements and instrumentalities shown. In the drawings:

FIG. **1** illustrates a top perspective view of an exemplary intervertebral implant according to the present invention, the implant illustrated in the collapsed, non-expanded or first insertion configuration

FIG. **2** illustrates a top perspective view of the intervertebral implant shown in FIG. **1**, the implant illustrated in a second, expanded configuration;

FIG. 3A illustrates a side elevational view of the intervertebral implant shown in FIG. 1, the implant illustrated in the collapsed, non-expanded or first insertion configuration;

FIG. 3B illustrates a side elevational view of the intervertebral implant shown in FIG. 1, the implant illustrated in the second expanded configuration;

FIG. 4A illustrates a top plan view of the intervertebral implant shown in FIG. 1, the implant illustrated in the collapsed, non-expanded or first insertion configuration;

FIG. 4B illustrates a top plan view of the intervertebral implant shown in FIG. 1, the implant illustrated in the second expanded configuration;

FIG. 5A illustrates a front elevational view of the intervertebral implant shown in FIG. 1, the implant illustrated in the collapsed, non-expanded or first insertion configuration;

FIG. 5B illustrates a front elevational view of the intervertebral implant shown in FIG. 1, the implant illustrated in the second expanded configuration;

FIG. 6A illustrates a top perspective view of a first preferred embodiment of a link member that may be used to form wire netting that may be used in conjunction with the intervertebral implant shown in FIG. 1;

FIG. 6B illustrates a top plan view of the wire netting shown in FIG. 6A, the wire netting illustrated in an at least partially collapsed, non-expanded or first insertion configuration;

FIG. 6C illustrates a top plan view of the wire netting shown in FIG. 6A, the wire netting illustrated in the second expanded configuration;

FIG. 7 illustrates a top perspective view of a second preferred embodiment of a link member that may be used to form wire netting that may be used in conjunction with the intervertebral implant shown in FIG. 1;

FIG. 8 illustrates a top perspective view of a third preferred embodiment of a link member that may be used to form wire netting that may be used in conjunction with the intervertebral implant shown in FIG. 1;

FIG. 9 illustrates a top perspective view of a fourth preferred embodiment of a link member that may be used to form wire netting that may be used in conjunction with the intervertebral implant shown in FIG. 1;

FIGS. 10A-10C illustrate various cross-sectional views of the intervertebral implant shown in FIG. 1, the superior and inferior bone contacting members incorporating wire netting so that the superior and inferior bone contacting members are able to adapt and/or conform to the endplates of the superior and inferior vertebral bodies V, respectively;

FIGS. 11A-11E illustrate various perspective views of steps of an exemplary surgical method for laterally inserting the expandable intervertebral implant of FIG. 1 in accordance with one aspect of the preferred invention; and

FIGS. 12A-12L illustrate various top, perspective views of steps of an exemplary method for manufacturing the expandable intervertebral implant of FIG. 1 in accordance with one aspect of the preferred invention.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Certain terminology is used in the following description for convenience only and is not limiting. The words "right", "left", "top" and "bottom" designate directions in the drawings to which reference is made. The words "inwardly" and "outwardly" refer to directions toward and away from, respectively, the geometric center of the device and designated parts thereof. The words, "anterior", "posterior", "superior", "inferior", "lateral" and related words and/or phrases designate preferred positions and orientations in the human body to which reference is made and are not meant to be limiting. The terminology includes the above-listed words, derivatives thereof and words of similar import.

Certain exemplary embodiments of the invention will now be described with reference to the drawings. In general preferred embodiments of the present invention are directed to (i) an expandable intervertebral implant **10** for implantation between or to replace damaged portions of adjacent vertebral bodies V in a patient's spine (for example, in the lumbar, thoracic or cervical regions), (ii) an exemplary surgical method for implanting the intervertebral implant **10** between adjacent vertebral bodies V in the patient's spine and (iii) an exemplary method of manufacturing the intervertebral implant **10**. More specifically, the present invention is preferably directed to an expandable intervertebral implant **10** for total or partial disc or vertebral body V replacement or for nucleus replacement of an intervertebral disc space S. It should be appreciated that while the expandable intervertebral implant **10** of the present application will be described in connection with spinal disc replacement, one of ordinary skill in the art will understand that the implant **10** as well as the components thereof may be used for replacement of tissue in other parts of the body including, for example, knee, hip, shoulder, finger or other joint replacement or for bone augmentation.

Referring to FIGS. 1-5B, as will be described in greater detail below, the expandable intervertebral implant **10** is preferably used for intervertebral support of the spine for patients that require interbody fusion at one or more levels of the spine. The expandable intervertebral implant **10** is preferably implanted by a surgeon into the patient's body in a collapsed, non-expanded or first insertion configuration (as best shown in FIGS. 1, 3A, 4A and 5A), thereby allowing a smaller incision than is typically necessary for implantation of a non-expandable intervertebral implant (not shown). Implantation of the preferred expandable intervertebral implant **10** in the first insertion configuration may also make it easier to insert the implant **10** past structures that may inhibit a surgeon's access to the spine. The expandable intervertebral implant **10** allows surgeons to implant a larger intervertebral implant in the disc space S, generally without having to do an excessive amount of boney resection and soft tissue retraction. Once the implant **10** is inserted into the disc space S, the implant **10** may be expanded to a second expanded configuration (as best shown in FIGS. 2, 3B, 4B and 5B). More preferably, the implant **10** is expandable in the cranio/caudal direction to provide parallel and/or lordotic intervertebral distraction and in the lateral direction. That is, the expandable intervertebral implant **10** is preferably implanted by a surgeon into the patient's body in a collapsed, non-expanded or first insertion configuration wherein the implant has a first height H_1 and a first width W_1. Thereafter, once inserted into the disc space S, the implant **10** may be expanded to a second expanded configuration wherein the implant **10** has a second height H_2 and a second width W_2, wherein the second height H_2 and the second width W_2 are larger than the first height H_1 and the first width W_1, respectively.

The preferred expandable intervertebral implant **10** may, for example, fill the entire intervertebral disc space S to replace the entire intervertebral disc. Alternatively, a plurality of expandable intervertebral implants **10** may be used to fill the intervertebral disc space S. For example, two or more smaller expandable intervertebral implants **10** may be used to fill the intervertebral disc space S. Alternatively, the expandable intervertebral implant **10** may be sized and configured to only partially replace an intervertebral disc space S, such as for example, to replace a nucleus. In addition, the preferred intervertebral implant **10** may be configured to replace a disc and a portion of a damages vertebra V.

The expandable intervertebral implant **10** preferably includes a superior bone contacting member **20** for contacting a first, superior vertebra V, an inferior bone contacting member **30** for contacting a second, inferior vertebra V and a vertical wire netting or mesh **50** for interconnecting the superior and inferior bone contacting members **20**, **30** with respect to one another. The vertical wire netting **50** preferably enables the superior and inferior bone contacting members **20**, **30** to move (e.g., expand) in the cranial/caudal direction or generally away from each other during movement from the collapsed, non-expanded or first insertion configuration to the second expanded configuration when the implant **10** is inserted into the disc space S. The superior and inferior bone contacting members **20**, **30** are sized and configured to contact at least a portion of the endplates of the superior and inferior vertebral bodies V, respectively, or to engage a surface of the superior and/or inferior vertebral bodies V remaining after damaged portions of the superior and/or inferior vertebrae V are removed from the spine. The superior and inferior bone contacting members **20**, **30** preferably define a cavity **40** therebetween.

The superior bone contacting member **20** of the exemplary preferred embodiment is formed by two or more bone contacting components **22** interconnected by a lateral wire netting or mesh **50'**. Similarly, the inferior bone contacting member **30** of the exemplary preferred embodiment is formed by two or more bone contacting components **32** interconnected by the lateral wire netting **50'**. That is, the superior and inferior bone contacting members **20**, **30** are each preferably constructed by a plurality of generally rigid bone contacting components **22**, **32** separated by or interconnected by the lateral expandable wire netting **50'** so that the bone contacting components **22**, **32**, which form the bone contacting members **20**, **30**, are moveable (e.g., expandable) with respect to one another. As shown, the bone contacting components **22**, **32** preferably are in the form of one or more plates, more preferably an L-shaped plate, although other shapes are contemplated. However, the bone contacting members **20**, **30** may be constructed as a single integral component, for example, if the implant **10** is constructed to expand only in the cranial/caudal direction. In addition, the superior and inferior bone contacting members **20**, **30** may have convex-shaped surfaces wherein they contact the endplates of the vertebra V to conform to the shape of the endplates.

In this manner, by incorporating the vertical wire netting **50** between the superior and inferior bone contacting members **20**, **30**, the implant **10** is expandable from the collapsed, non-expanded or first insertion configuration wherein the implant **10** has a first height H_1 to the second expanded configuration wherein the implant **10** has a second height H_2, wherein the second height H_2 is larger than the first height H_1. Similarly, by incorporating the lateral wire netting **50'** between the adjacent bone contacting components **22**, **32**, which form the superior and inferior bone contacting members **20**, **30**, respectively, the implant **10** is expandable from the collapsed, non-expanded or first insertion configuration wherein the implant **10** has a first width W_1 to a second expanded configuration wherein the implant **10** has a second width W_2, wherein the second width W_2 is larger than the first width W_1. That is, the lateral wire netting **50'** preferably enables the bone contacting components **22**, **32** to be laterally moveable (e.g., in the anterior-posterior or lateral direction depending on insertion procedure) with respect to one another along a lateral axis **A2** while the vertical wire netting **50** enables the superior and inferior bone contacting members **20**, **30** to be vertically moveable with respect to one another along a vertical axis **A3**. In addition, the vertical and lateral wire netting **50**, **50'** enables the superior bone contacting member **20** to move with respect to the inferior bone contacting member **30** along a longitudinal axis **A1**. Thus, the vertical and lateral wire netting **50**, **50'** enables the implant **10** to conform its final shape in the second or expanded configuration to mate to the typically uneven surfaces of the endplates of the vertebral bodies V. In addition, the vertical and lateral wire netting **50**, **50'** enables the implant **10** to limit stress risers at contact points between the implant **10** and the vertebral bodies V thus making the preferred implant **10** applicable for insertion between osteoporotic bone.

That is, in the preferred embodiment, by forming the preferred implant **10** from four bone contacting components **22**, **32** interconnected by vertical and lateral wire netting **50**, **50'**, the superior and inferior bone contacting members **20**, **30** of the implant **10** are preferably able to move in six degrees of freedom with respect to each other. Specifically, the superior and inferior bone contacting members **20**, **30** are able to move longitudinally relative to each other along the longitudinal axis **A1**, laterally relative to each other along the lateral axis **A2**, vertically relative to each other along the vertical axis **A3**, pivot or roll relative to each other about the longitudinal axis **A1**, pivot or pitch relative to each other about the lateral axis **A2** and pivot or yaw relative to each other about the vertical axis **A3**. Accordingly, the preferred implant **10** is able to conform its final shape in the second or expanded configuration to mate to the typically uneven surfaces of the endplates of the vertebral bodies V and limit stress risers at contact points between the implant **10** and the vertebral bodies V.

It should be noted that it is also envisioned that the superior and inferior bone contacting members **20**, **30** may be formed of four or more bone contacting components **22**, **32** interconnected by lateral wire netting **50'** and longitudinal wire netting (not shown) so that the implant **10** is longitudinally moveable from a first length to a second length (not shown). Alternatively, the superior and inferior bone contacting members **20**, may be formed of two bone contacting components **22**, **32** interconnected by longitudinal wire netting (not shown) but not lateral wire netting **50'** so that the implant **10** is longitudinally moveable from a first length to a second length (not shown) but not laterally moveable from the first width W_1 to the second width w_2.

The vertical wire netting **50** and the lateral wire netting **50'**, preferably enable approximately three tenths of a millimeter (0.3 mm) to approximately twelve millimeters (12 mm) of movement, although other amounts of movement are permissible as would be apparent to one having ordinary skill in the art. Further, the implant is not limited to having the generally rectangular or box-shaped configuration shown in FIGS. **1**-**12**L, for example, the implant **10** may have a generally circular or cylindrical-shaped series of rings that form the superior and inferior bone contacting members **20**, **30** separated by wire netting such that an inner ring may expand along the vertical axis **A3** further than an outer ring to conform to a concave-shaped endplate.

Referring to FIGS. **6**A-**6**C, a first preferred, exemplary embodiment of the vertical and/or lateral wire netting **50**, **50'** is formed by interconnecting a plurality of individual first link members **52**. As shown, the plurality of individual first link members **52** may have a generally rectangular shape when at least partially expanded but are not so limited. Referring to FIG. **7**, a second preferred exemplary embodiment of the lateral and/or vertical wire netting **50**, **50'** may be formed by interconnecting a plurality of individual second link members **52'** wherein the plurality of individual second link members **52'** have a generally trapezoidal shape when at least partially expanded but are not so limited. Referring to FIG. **8**, a third preferred, exemplary embodiment of the vertical and/or lateral wire netting **50**, **50'** may be formed by interconnecting a plurality of individual third link members **52"** wherein the plurality of individual think link members **52"** have an alternate, second rectangular shape when at least partially expanded but are not so limited. Referring to FIG. **9**, a fourth preferred, exemplary embodiment of the vertical and/or lateral wire netting **50**, **50'** may be formed by interconnecting a plurality of individual fourth link members **52'''** wherein the plurality of individual fourth link members **52'''** have an alternate, third rectangular shape when at least partially expanded but are not so limited. Alternatively, the vertical and/or lateral wire netting **50**, **50'** may have any other form or shape such as, for example, a plastically deformable material, mesh, stent, etc. so long as the vertical and/or lateral wire netting **50**, **50'** interconnects and enables the superior and inferior bone contacting members **20**, and/or the superior and inferior bone contacting components **22**, **32** to move with respect to one another. The preferred individual link members **52**, **52'**, **52"**, **52'''** are not limited to the generally rectangular or trapezoidal shapes and may take nearly any shape such as, for example, oval, circular, triangular, hexagonal, etc.

In addition, by forming or constructing the vertical and/or lateral wire-netting **50**, **50'** from a plurality of preferred individual first, second, third and/or fourth link members **52**, **52'**, **52"**, **52'''** the superior and/or inferior bone contacting components **22**, **32** are able to tilt or generally move with respect to one another so that the superior and inferior bone contacting members **20**, **30** are better able to conform to the configuration of the endplates of the adjacent vertebral bodies V. That is, as previously described above, by forming the preferred implant **10** from four bone contacting components **22**, **32** interconnected by vertical and lateral wire netting **50**, **50'**, the flexible of the vertical and/or lateral wire netting **50**, **50'** enables the superior and inferior bone contacting members **20**, **30** of the implant **10** to move in six degrees of freedom with respect to each other so that the implant **10** and more particularly the superior and inferior bone contacting members **20**, **30** are better able to adapt and/or conform to the anatomical shape of the endplates of the superior and inferior vertebral bodies V, respectively. As illustrated in FIGS. **10A**-**10C**, the superior and inferior bone contacting components **22**, **32** are better able to adapt and/or conform to the endplates of the superior and inferior vertebral bodies V, respectively, due to the inherent flexibility or adaptability of forming the superior and inferior bone contacting members **20**, **30** from multiple components **22**, **32** interconnected by a flexible wire netting **50**, **50'**. Thus, in use, the lateral wire netting **50'** enables the superior bone contacting components **22** to move with respect to one another and enables the inferior bone contacting components **32** to move with respect to one another such that the lateral wire netting **50'** enables the superior and inferior bone contacting members **20**, **30** to adapt and/or conform to the endplates of the superior and inferior vertebral bodies V, respectively.

The preferred implant **10** also includes a cavity **40** located between the superior and inferior bone contacting members **20**, **30**. The cavity **40** is preferably sized and configured to receive a filling material (not shown) and/or a balloon **75**, an expansion sack, an expansion bag, etc. (collectively referred to herein as an "expansion member"). The expansion member **75** is preferably sized and configured to be received within the cavity **40** in order to limit any filling material from overflowing and escaping from the cavity **40**. More preferably, as will be described in greater detail below, once the implant **10** has been implanted and positioned, the expansion member **75** is preferably inserted into the cavity **40**. Thereafter, the filling material may be inserted into the expansion member **75**, expanding the expansion member **75** so that the implant **10** is expanded from the collapsed, non-expanded or first insertion configuration to the second expanded configuration. Once inserted, the filling material preferably hardens or is cross-linked in order to support the implant **10** in the second expanded configuration. Alternatively, the filling material may not harden and may partially harden into a gel-like material or may retain a flowable or liquid state and become sealed in the expansion member **75**.

It should be noted that expanding of the expansion member **75** may or may not cause distraction of the adjacent vertebral bodies V. However, the flexibility of the expansion member **75** and the sequential hardening of the filling material preferably provide a geometrically adapted restoration of the intervertebral disc space S. Alternatively, the filling material may remain in a gel and/or liquid state and may be sealed in the expansion member **75**. In addition, as will be generally appreciated by one of ordinary skill in the art, the expansion member **75** may be inserted into the cavity **40** prior to implantation of the implant **10**, the filling material may be injected into the expansion member **75** prior to implantation of the implant **10**, the expansion member **75** may be integrated with or coupled to the implant **10**, and/or the expansion member **75** may be omitted entirely.

Moreover, it should be understood that the superior and inferior bone contacting members **20**, **30** may include any number of bone contacting components **22**, **32** and interconnecting lateral wire netting **50'** such as, for example, three bone contacting components **22**, **32** interconnected by two lateral wire nettings **50'**. It is also envisioned that the implant **10** may include one or more intermediate components (not shown) between the superior and inferior bone contacting members **20**, **30**. The intermediate components may be coupled to the superior and inferior bone contacting members **20**, **30** via the vertical wire netting **50**. Moreover, it is also envisioned that the implant **10** may include the vertical wire netting **50** to enable cranio/caudal expansion without incorporating the lateral wire netting **50'**. Alternatively, the implant **10** may include the lateral wire netting **50'** to enable lateral expansion without incorporating the vertical wire netting **50**.

The superior and inferior bone contacting members **20**, **30** may include means for increasing the stability of the implant **10**, such as, for example, one or more projections, one or more roughened surfaces, one or more undulating structures, one or more ridges, one or more keels, etc. Preferably, the superior and inferior bone contacting members **20**, **30** include a plurality of teeth **21** for increasing the stability of the implant **10**.

The implant **10** may also include a mechanism or feature for engaging an implant insertion instrument (not shown). The mechanism or feature for engaging the insertion instrument may take on any form now or hereafter known including, for example, one or more bores **102** for receiving one or more projections (not shown) formed on the implant insertion instrument, one or more projections (not shown) for engaging one or more bores (not shown) formed on the implant insertion instrument, one or more channels (not shown) for receiving one or more tips formed on the implant insertion instrument, one or more threaded bores (not shown) for receiving one or more threaded shafts or screws, etc.

The implant **10** may also include a mechanism or features for reducing and/or preventing shearing or dismantling of the implant **10** during insertion such as, for example, the superior and inferior bone contacting members **20**, **30** may include interconnecting projections **24** and bores **34** for temporarily securing the implant **10** in its collapsed or insertion configuration.

The superior and inferior bone contacting members **20**, **30** may be formed from any biocompatible material including, but not limited to, a metal, such as, for example, cobalt-chromium-molybdenum (CCM) alloys, titanium, titanium alloys, stainless steel, aluminum, etc., a ceramic such as, for example, zirconium oxide, silicone nitride, etc., an allograft, an autograft, a metal-allograft composite, a polymer such as, for example, polyaryl ether ketone (PAEK), polyether ether ketone (PEEK), polyether ketone ketone (PEKK), polyetherketone (PEK), polyetherketone ether-ketone-ketone (PEK-EKK), etc. The polymers may be reinforced with a fiber such as, for example, a carbon fiber or other thin, stiff fiber.

The superior and inferior bone contacting members **20**, **30** may also be coated in order to enhance their osteo-conductive properties. For example, the bone contacting members **20**, **30** may be coated with an etching, anodization, an anodic plasma chemical process, electrolytic deposition, plasma spraying, a thin layer of titanium (Ti) via a physical or chemical vapor deposition process, an anodic plasma chemical surface treatment incorporating, for example, Ca and/or P in the Ti-Oxide surface layer or via a Ti or HA plasma spray, etc.

The expansion member **75** may be manufactured from any biocompatible material including, but not limited to, a polyurethane, a polycarbonate urethane, a poly carbonate-silicone urethane copolymer, polyamine, polyethylene terephthalate (PET), polycaprolactone, etc.

The filling material may be any biocompatible material known in the art and may be a rigid or elastic material. The filling material may be comprised of, for example, a bone cement, a hydrogel, a polyvinyl alcohol, a sodium polyacrylate, an acrylate polymer, a methyl-methacrylate, a co-polymer with an abundance of hydrophilic groups, p-vinyl pyrollidone, polyethyleneimine, etc., a setting or curing hydrogel based co-polymer such as, for example, polyethyleneimine, poly(diethylaminoethyl methacrylate), poly (ethylaminoethyl methacrylate), etc., a thermally setting hydrogel based co-polymers, such as, for example, poly-N-isopropylacrylamide with polyethylene glycol, copolymers of polyethylene oxide and polyphenelylene oxide, copolymers of polyethylene glycol and polyactides, etc., an ionic setting hydrogel such as, for example, ethylacrylate, methacrylic acid, 1,4-butanediacrylate, etc., or a PCU, PCU-silicone co-polymer, silicone or other non-resorbable pure or elastic co-polymer (e.g., PCU's silicone end group modified PU's, RTV curing siloxane based elastomers, etc.).

Exemplary Method of Inserting the Intervertebral Implant.

The expandable intervertebral implant **10** may be inserted within the targeted intervertebral disc space S by any means, method, or approach now or hereafter known in the art including, but not limited to, via anterior, lateral, posterior, anterior-lateral, or posterior-lateral approaches, etc. Preferably, the implant **10** is implanted using a minimally invasive technique. Alternatively, the implant **10** may be implanted via an open incision, as would be appreciated by one having ordinary skill in the art.

Referring to FIGS. **11**A-**11**E, in one exemplary method of inserting the implant **10** via a lateral approach, the implant **10** is inserted into the intervertebral disc space S between adjacent superior and inferior vertebral bodies V via an insertion instrument (not shown). As illustrated in FIG. **11**A, the implant **10** is preferably inserted into the intervertebral disc space S in the collapsed, non-expanded or first insertion configuration following a preferably minimal incision through the skin to the disc space S. As illustrated in FIG. **11**B, the implant **10** is preferably positioned within the intervertebral disc space S at least partially in a posterior direction in order to generally keep the motion segment in balance. More preferably, the implant **10** should be positioned so that the implant **10** engages the stronger peripheral aspects of the adjacent vertebral bodies V. Once the implant **10** has been properly positioned in its desired location, as illustrated in FIG. **11**C, the implant **10** is preferably laterally expanded in the anterior-posterior direction (in the lateral direction if the implant **10** was inserted via an anterior or posterior approach) via a surgical instrument (not shown). Alternatively, the implant **10** may be inserted with the expansion member or balloon **75** therein and laterally expanded via the expansion member **75**. Preferably, the implant's position should be checked at this point to ensure preferred positioning. Once the position of the implant **10** is verified based generally on surgeon preference and/or physiology, as illustrated in FIG. **11**D, the expansion member **75** is inserted and positioned within the cavity **40** formed in the implant **10** via an insertion instrument (not shown). The implant **10** may be slightly expanded via the implant insertion instrument in order to ease insertion of the expansion member **75** within the cavity **40**, if necessary. Next the expansion member **75** is filled with a filling material, which causes the implant **10** to expand in the cranio/caudal direction, preferably resulting in the implant **10** firmly penetrating into the endplates of the adjacent superior and inferior vertebral bodies V. Due to the adaptability of the vertical and/or lateral wire netting **50**, **50'**, the superior and inferior bone contacting members **20**, **30** of the implant **10** may substantially mate to the typically uneven surfaces of the endplates of the superior and inferior vertebral bodies V, respectively. For example, the individual bone contacting members **22**, **32** may move linearly relative to each other along the longitudinal, lateral and/or vertical axes A**1**, A**2**, A**3** and may pivot relative to each other about the longitudinal, lateral and/or vertical axes A**1**, A**2**, A**3** such that the shape of the implant **10** in the expanded configuration conforms to the anatomical shape of the pre-existing endplates of the vertebrae V. Specifically, each of the bone contacting members **22**, **32** are movable relative to each other in six degrees of freedom to permit the individual components to adapt their final position to the patient's anatomy, thereby reducing stress risers that may develop when an implant is unable to conform to the shape of the anatomy.

Exemplary Method of Manufacturing the Intervertebral Implant

The preferred expandable intervertebral implant **10** may be manufactured by any means and/or method now or hereafter known in the art including, but not limited to, by manufacturing each of the bone contacting members **20**, **30** as separate and distinct components and then coupling each of the components to vertical and lateral wire netting **50**, **50'**, as required.

Preferably, however, the implant **10** is formed as an integral implant manufactured via a layer-wise or layer by layer manufacturing process. For example, referring to FIGS. **12**A-**12**L, the implant **10** preferably is manufactured via a selective laser melting process. The metal components are preferably set up in layers, similar to a stereo-lithograph. In use, a thin layer of metal powder is applied to a platform. The powder is then locally melted by, for example, a laser beam. The platform is then lowered by a defined layer height. Another thin layer of metal powder is then applied. The second layer of powder is then locally melted. This process is repeated until the implant **10** is complete. The ability to manufacture the implant **10** as a single or integral component or part permits the manufacture of continuous loops or solid vertical and lateral wire netting **50**, **50'** between the bone contacting components **22**, **32**. In contrast, alternate techniques for constructing the vertical and lateral wire netting **50**, **50'** may require joining together of ends of the wires to construct the preferred first, second, third and fourth link members **52**, **52'**, **52''**, **52'''**.

Alternatively, the implant **10** may be manufactured via a selective laser sintering process. Generally, the laser sintering process follows the same steps as the selective laser melting process described above. However since sintering is performed below the melting point of the substrate material, the laser sintering process allows the original metal powder to be mixed with a binding agent. A steam stripping process may be used after the laser sintering process. Using the laser sintering process, combinations of metals as well as microporous structures can be manufactured. The laser sintering process may also be used in connection with thermoplastic polymers which do not have any specific melting point but rather have a transition zone between a glass transition temperature and a melt mass temperature.

While laser melting and sintering processes have been described, other manufacturing methods are contemplated including, but not limited to, other methods of curing or sintering such as, for example, the use of ultrasonic or ultraviolet rays.

Features described herein may be used singularly or in combination with other features. In addition, features disclosed in connection with one embodiment may be interchangeable with a feature or features disclosed in another embodiment. Therefore the presently disclosed embodiments are to be considered as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, and not limited to the foregoing description.

It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

What is claimed:

1. A method of implanting an intervertebral implant comprising the steps of:

inserting the intervertebral implant into an intervertebral space along a lateral surgical approach while the intervertebral implant is in a collapsed configuration having a first height, such that 1) a superior bone contacting member of the intervertebral implant faces a superior vertebral body and an inferior bone contacting member of the intervertebral implant faces an inferior vertebral body that cooperate to define the intervertebral space, and 2) the superior bone contacting member of the intervertebral implant abuts the inferior bone contacting member of the intervertebral implant so as to prevent movement of the superior and inferior bone contacting members toward each other;

causing an expansion member that is disposed between the superior bone contacting member and the inferior bone contacting member to expand the intervertebral implant in the intervertebral space to an expanded configuration having a second height greater than the first height, wherein at the second height the superior bone contacting member bears against the superior vertebral body, and the inferior bone contacting member bears against the inferior vertebral body, and

tilting at least one of the superior and inferior bone contacting members relative to the other of the superior and inferior bone contacting members along an anterior-posterior direction to achieve intervertebral lordotic distraction.

2. The method as recited in claim **1**, comprising performing the tilting step after the causing step.

3. The method as recited in claim **2**, further comprising the step of expanding a width of the intervertebral implant along a third direction perpendicular to the lateral surgical approach and a direction of expansion of the intervertebral implant to the expanded configuration.

4. The method as recited in claim **1**, wherein the implant has a length along the lateral surgical approach and a width along a third direction that is perpendicular to each of the lateral surgical approach and a direction of expansion of the intervertebral implant to the expanded configuration, and the length is greater than the width.

5. The method as recited in claim **1**, wherein the tilting step comprises conforming the superior and inferior bone contacting members to respective endplates of the superior and inferior vertebral bodies, respectively.

6. The method as recited in claim **1**, further comprising the step of engaging teeth of the superior and inferior bone contacting members with the superior and inferior vertebral bodies, respectively.

7. The method as recited in claim **1**, further comprising, prior to the step of inserting:

accessing the intervertebral space defined by the superior and inferior vertebral bodies that neighbor each other so as to define the intervertebral space; and

after the accessing step, removing at least a portion of a disc from the intervertebral space so as to produce the intervertebral space.

8. A method of implanting an intervertebral implant comprising the steps of:

accessing an intervertebral disc space defined by neighboring superior and inferior vertebral bodies;

removing disc material from the intervertebral disc space so as to produce an intervertebral space;

inserting the intervertebral implant into the intervertebral disc space along a lateral surgical approach while the intervertebral implant is in a collapsed configuration having a first height, such that a superior bone contacting member of the intervertebral implant faces the superior vertebral body and an inferior bone contacting member of the intervertebral implant faces the inferior vertebral body;

expanding the intervertebral implant in the intervertebral space to an expanded configuration having a second height greater than the first height, whereby the superior bone contacting member bears against the superior vertebral body, and the inferior bone contacting member bears against the inferior vertebral body, and tilting at least one of the superior and inferior bone contacting members relative to the other of the superior and inferior bone contacting members along an anterior-posterior direction to achieve intervertebral lordotic distraction.

9. The method as recited in claim **8**, wherein the superior bone contacting member contacts the inferior bone contacting member during the inserting step.

10. The method as recited in claim **8**, further comprising performing the tilting step after the expanding step.

11. The method as recited in claim **10**, further comprising the step of expanding a width of the intervertebral implant along a third direction perpendicular to the lateral surgical approach and a direction of expansion of the intervertebral implant to the expanded configuration.

12. The method as recited in claim **8**, wherein the implant has a length along the lateral surgical approach and a width along a third direction that is perpendicular to each of the lateral surgical approach and a direction of expansion of the intervertebral implant to the expanded configuration, and the length is greater than the width.

13. The method as recited in claim **8**, wherein the tilting step comprises conforming the superior and inferior bone contacting members to respective endplates of the superior and inferior vertebral bodies, respectively.

14. The method as recited in claim **8**, further comprising the step of engaging teeth of the superior and inferior bone contacting members with the superior and inferior vertebral bodies, respectively.

15. The method as recited in claim **8**, wherein the removing step is performed prior to the inserting step.

16. The method as recited in claim **8**, wherein the expanding step comprises expanding an expansion member disposed between the superior and inferior bone contacting memebers, wherein the expansion member is separate from each of the superior and inferior bone contacting members.

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